United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, Plaintiff, v. ALEX AZAR, et al., Defendants.	Case No. 19-cv-01184-EMC **RELATED TO** Case No. 19-cv-01195-EMC
ESSENTIAL ACCESS HEALTH, INC., et al., Plaintiffs, v. ALEX M. AZAR II, et al., Defendants.	**ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION** Docket No. 26, C-19-1184 Docket No. 25, C-19-1195

Title X of the Public Health Service Act provides federal funding for family-planning services. In the quarter-century since 1993, the Department of Health and Human Services' ("HHS") guidelines, while prohibiting funding of abortion services pursuant to Title X, have required Title X grantees to provide neutral, factual counseling to pregnant clients and to maintain financial separation between their Title X activities and their abortion services. This permitted grantees to operate effectively while complying with Title X. On March 4, 2019, HHS promulgated new regulations implementing Title X which substantially changes those guidelines in a manner that jeopardizes the provision of essential and counseling and care to thousands of women. *See* 84 Fed. Reg. 7714 (2019) (the "Final Rule"). According to Plaintiffs, the Final Rule will create daunting barriers to California women seeking timely, effective reproductive health

care, impose medically and ethically unsound restrictions on Title X providers attempting to provide patient-centered care, and inflict severe public health consequences and costs on the State. They contend the Final Rule violates recent acts of Congress, substantive and procedural provisions of the Administrative Procedures Act ("APA"), and the First and Fifth Amendments to the U.S. Constitution.

The Final Rule goes into effect on May 3, 2019. Plaintiffs in these coordinated actions, the State of California and Essential Access Health, seek to preliminarily enjoin the implementation of the Final Rule.

Unless enjoined, the Final Rule will irreparably harm individual patients and public health in California as a whole. The Final Rule commands medical professionals to provide incomplete and misleading information to women seeking to terminate their pregnancies contrary to what patients want and need, delaying and potentially frustrating their attempts to obtain time-sensitive care, and thereby jeopardizing their health and welfare. The Final Rule threatens to decimate the network of Title X providers in California and drastically restrict patients' access to a wide range of vital services, including contraceptive resources and screenings for sexually transmitted infections, reproductive cancers, and HIV. As a result, the Final Rule is likely to inflict significant public health consequences and costs on the State and frustrate Essential Access's organizational mission to promote access to quality healthcare. In contrast, Defendants are unable to articulate any real harm they will suffer if the Final Rule is preliminarily enjoined during the pendency of this action.

Plaintiffs have shown that the Final Rule likely violates Congressional directives that Title X providers must be permitted to give pregnant patients neutral, factual information regarding the full range of their medical options, and must not be compelled to act in a way that is contrary to medical ethics. The record evidence indicates that HHS promulgated the Final Rule, which represents a sharp break from prior policy, without engaging in any reasoned decisionmaking. In particular, HHS cited speculative, unsubstantiated fears about the misuse of Title X funds as justification for its change in policy and touted anticipated benefits of the Final Rule that have no basis in the record, while cursorily dismissing overwhelming evidence of the significant adverse

impact the Rule will have. The Final Rule is thus contrary to law and arbitrary and capricious.

Having considered the parties' briefs and accompanying submissions, as well as the oral argument of counsel and amici briefs filed herein, the Court finds that Plaintiffs have established they are likely to succeed on the merits on several of their claims, are likely to suffer irreparable injury if the Final Rule is not enjoined, and the balance of hardships and the public interest tip sharply in favor of granting injunctive relief. Accordingly, Plaintiffs' motions for a preliminary injunction are **GRANTED in part and DENIED in part**.[1] The Court enjoins implementation of the Final Rule but limits the injunction to California.

I. BACKGROUND

A. Statutory and Regulatory Background

1. Title X

The Public Health Service Act ("PHSA"), an expansive statutory scheme that consolidated existing public health laws and established various agencies and grant programs to support health care and research, was enacted in 1944. In 1970, Congress amended the PHSA to add "Title X—Population Research and Voluntary Family Planning Programs." Pub. L. No. 91-572, § 6, 84 Stat. 1504, 1506–08 (1970) (codified at 42 U.S.C. §§ 300–300a-6). Title X authorizes the Secretary of HHS "to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). Such grants and contracts must "be made in accordance with such regulations as the Secretary may promulgate." *Id.* § 300a-4. Congress explained that its purpose in enacting Title X was:

> a. to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services;

[1] The recent injunction issued against Defendants' implementation of the Final Rule by Judge Bastian in *State of Washington v. Azar*, No. 1:19-cv-3040 (E.D. Wash. filed Mar. 5, 2019), does not obviate this Court's duty to resolve the dispute before it. *See Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 435 (E.D.N.Y. 2018) (finding "no authority for the proposition that Plaintiffs cannot establish irreparable harm simply because another court has already enjoined the same challenged action"); *e.g.*, *Kravitz v. United States Dep't of Commerce*, 366 F. Supp. 3d 681 (D. Md. 2019); *State v. Ross*, 358 F. Supp. 3d 965, 1050 (N.D. Cal. 2019); *Nat'l Ass'n for the Advancement of Colored People v. Trump*, 315 F. Supp. 3d 457, 461 (D.D.C. 2018).

b. to coordinate domestic population and family planning research with the present and future needs of family planning programs;

c. to improve administrative and operational supervision of domestic family planning services and of population research programs related to such services;

d. to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services;

e. to develop and make readily available information (including educational materials) on family planning and population growth to all persons desiring such information;

f. to evaluate and improve the effectiveness of family planning service programs and of population research; [and]

g. to assist in providing trained manpower needed to effectively carry out programs of population research and family planning services . . . .

Pub. L. No. 91-572 § 2, 84 Stat. 1504.

Per Section 1008 of the PHSA, "[n]one of the funds appropriated under [Title X] shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6.

2. The 1971 Regulations, 1981 Guidance, 1988 Regulations, and *Rust v. Sullivan*

Consistent with Section 1008, HHS has never permitted Title X grantees to use Title X funds to perform or subsidize abortions. *See* 42 C.F.R. §§ 59.5(a)(5), 59.9 (1986). However, the agency had long interpreted Title X to allow grantees to provide pregnant women with nondirective counseling and referrals about their medical options, including abortion. The initial regulations, issued in 1971, stated that Section 1008 only required that a Title X "project will not provide abortions as a method of family planning." 36 Fed. Reg. 18,465, 18,466 (1971). "During the mid-1970s, HHS General Counsel memoranda made a further distinction between directive ('encouraging or promoting' abortion) and nondirective ('neutral') counseling on abortion, prohibiting the former and permitting the latter." *Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 229 (D.C. Cir. 1992). This distinction was reaffirmed in 1981, when HHS issued guidelines "requir[ing] nondirective 'options counsleling' [*sic*] on pregnancy termination (abortion), prenatal care, and adoption and foster care when a woman with an unintended pregnancy requests information on her options, followed by referral for these services if she so requests." 53 Fed. Reg. 2922, 2923 (1988). Thus, early on, HHS distinguished

nondirective counseling (and referrals) from the actual provision of abortion services, permitting the former but prohibiting the latter.

That policy was reversed in 1988 when HHS promulgated new regulations to provide "'clear and operational guidance' to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning." *Id.* at 2923–24. The term "family planning" was redefined to encompass solely "preconceptional counseling, education, and general reproductive health care," while expressly excluding "pregnancy care (including obstetric or prenatal care)." 42 C.F.R. § 59.2 (1989).

The thrust of the 1988 regulations was reflected in three main provisions. First, they provided that a "Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning," even in response to a client's specific request. *Id.* § 59.8(a)(1). Second, the regulations prohibited a Title X project from engaging in any activities that "encourage, promote or advocate abortion as a method of family planning." *Id.* § 59.10(a). Third, Title X projects were required to be "physically and financially separate" from prohibited abortion activities. *Id.* § 59.9. The regulations enumerated nonexclusive factors for the Secretary of HHS to consult in determining whether the separation requirement was met, including the existence of separate accounting records and separate personnel, and the degree of physical separation of the project from facilities for prohibited activities. *Id.* The regulations made clear that "[m]ere bookkeeping separation of Title X funds from other monies is not sufficient." *Id.*

The 1988 regulations were subject to legal challenge, and were upheld by the Supreme Court against a facial challenge by Title X grantees in *Rust v. Sullivan*, 500 U.S. 173 (1991). The *Rust* plaintiffs objected to the regulations on statutory and constitutional grounds. They argued that the regulations were arbitrary and capricious and exceeded the Secretary's authority under Title X, that the regulations' proscription of abortion counseling and referral violated the First Amendment, and that the regulations violated a woman's Fifth Amendment right to choose whether to terminate her pregnancy. *Id.* at 183, 192, 201.

The Supreme Court found none of these claims availing. It rejected the plaintiffs' first

statutory claim after applying *Chevron* deference to the Secretary's construction of Title X. The Court determined that statutory text and legislative history of Title X were ambiguous regarding abortion counseling and referral as well as the separation of Title X and non-Title X services. *Id.* at 184 ("The language of § 1008—that '[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning'—does not speak directly to the issues of counseling, referral, advocacy, or program integrity."). In the face of that ambiguity, the Court decided that the Secretary's construction of the statute "to require a ban on counseling, referral, and advocacy within the Title X project" was reasonable, noting that the "broad language" of "§ 1008 prohibits the use of Title X funds 'in programs where abortion is a method of family planning'" and that "the legislative history is ambiguous and fails to shed light on relevant congressional intent." *Id.* at 184–85. Similarly, the Court ruled that the Secretary's construction of Title X to require physical and financial separation between Title X projects and abortion activities was permissible. *Id.* at 188–90. Importantly, even after finding the 1988 regulations facially reasonable under *Chevron*, the Court required the Secretary to justify his change of interpretation from the prior rules with a "reasoned analysis." *Id.* at 187 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983)). In this regard, the Court observed that the Secretary's decision to reverse course from the prior regulations was justified in part because it responded to "critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG) that prior policy failed to implement properly the statute and that it was necessary to provide 'clear and operational guidance to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning,'" as well as "client experience under the prior policy" and "a shift in attitude against the elimination of unborn children by abortion." *Id.* (quoting 53 Fed. Reg. at 2923–24).

Rust further held that the regulations did not "violate the First Amendment by impermissibly discriminating based on viewpoint" because "[t]he Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest, without at the same time funding an alternative program which seeks to deal with the problem in another way." *Id.* at 192–93. The Court noted its previous holding that

"the government may 'make a value judgment favoring childbirth over abortion, and . . . implement that judgment by the allocation of public funds.'" *Id.* (quoting *Maher v. Roe*, 432 U.S. 464, 474 (1977)) (alteration in original). *Rust* thus determined that "[t]he Secretary's regulations do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities." *Id.* at 196. Grantees "remain[ed] free . . . to pursue abortion-related activities when they [we]re not acting under the auspices of the Title X project." *Id.* at 198. The Court cautioned, however, that it was "not . . . suggest[ing] that funding by the Government, even when coupled with the freedom of the fund recipients to speak outside the scope of the Government-funded project, is invariably sufficient to justify Government control over the content of expression." *Id.* at 199.

Lastly, the Court ruled that the 1988 regulations did not impermissibly burden a woman's Fifth Amendment right to choose whether to terminate her pregnancy. Citing the principle that "the Due Process Clauses generally confer no affirmative right to governmental aid," the Court held that "[t]he Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected and may validly choose to fund childbirth over abortion." *Id.* at 201 (quoting *Webster v. Reprod. Health Servs.*, 492 U.S. 490, 507 (1989)). In support of this holding, *Rust* reasoned that "[t]he difficulty that a woman encounters when a Title X project does not provide abortion counseling or referral leaves her in no different position than she would have been if the Government had not enacted Title X." *Id.* at 202. The Court also found unpersuasive the plaintiffs' contention that "the regulations violate a woman's Fifth Amendment right to medical self-determination and to make informed medical decisions free of government-imposed harm" by "depriving a Title X client of information concerning abortion as a method of family planning." *Id.* The Court observed that under the regulations, "a doctor's ability to provide, and a woman's right to receive, information concerning abortion and abortion-related services outside the context of the Title X project remains unfettered." *Id.* at 203.

3. 1993 Suspension of the 1988 Regulations and Promulgation of the 2000 Regulations

Although they survived legal challenges, the 1988 regulations were never fully

implemented. The Secretary suspended the regulations in 1993 "based, in part, upon her conclusion that the 'Gag Rule' is an inappropriate implementation of the Title X statute because it unduly restricts the information and other services provided to individuals under this program." 58 Fed. Reg. 7462, 7462 (1993). As a result, after 1993, Title X grantees returned to operating under the 1981 guidelines.

In 2000, HHS formally issued new regulations "revoking the regulations published on February 2, 1988" and largely restoring the 1981 regulatory scheme. 65 Fed. Reg. 41270 (2000); 65 Fed. Reg. 41281 (2000). Most notably, under the 2000 regulations, Title X grantees were required to "[o]ffer pregnant women the opportunity to be provided information and counseling regarding . . . [p]regnancy termination" and "provide neutral, factual information and nondirective counseling on each of the options, and referral" upon request. 42 C.F.R. § 59.5(a)(5) (July 3, 2000). Grantees' non-Title X abortion activities had to be "separate and distinct" from Title X activities, but "[c]ertain kinds of shared facilities [we]re permissible, so long as it [wa]s possible to distinguish between the Title X supported activities and non-Title X abortion-related activities." 65 Fed. Reg. at 41281. For example, common waiting rooms and staff were permissible, as long as the costs and salaries were properly pro-rated and allocated. *Id.* The agency provided the following explanation for doing away with the physical separation requirement:

> If a Title X grantee can demonstrate by its financial records, counseling and service protocols, administrative procedures, and other means that—within the identified set of Title X-supported activities—promotion or encouragement of abortion as a method of family planning does not occur, then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for "physical" separation. Indeed, in the light of the enforcement history noted above, it is not unreasonable to say that the standard of "physical" separation has, as a practical matter, had little relevance or applicability in the Title X program to date. Moreover, the practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the Gag Rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services.

65 Fed. Reg. at 41276.

4. Statutory Developments

Two statutory developments since *Rust* are germane to this case. First, in every year since

1996, Congress has specified in HHS appropriations acts (part of annual omnibus appropriations acts containing a subsection specific to HHS funding) that "amounts provided to [Title X] projects under such title shall not be expended for abortions, [and] that *all pregnancy counseling shall be nondirective*." *E.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, Pub. L. No. 115-245, Div. B, Tit. II, 132 Stat 2981, 3070–71 (2018) (emphasis added).

Second, in Section 1554 of the Affordable Care Act ("ACA"), enacted in 2010, Congress directed that HHS:

> shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
>
> (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114. As discussed below, these laws affect the enforcement of Title X.

B. The Final Rule

On March 4, 2019, HHS promulgated the Final Rule that is the subject of this suit. 84 Fed. Reg. 7714. The Final Rule represents a sharp break from the 2000 regulations, and a return in many aspects to the 1988 regulations. Its key provisions are detailed below.

1. Restrictions on Abortion Counseling and Referrals

The Final Rule contains several overlapping provisions regarding abortion counseling. It directs that Title X grantees may "[n]ot provide, promote, refer for, or support abortion as a

method of family planning." 42 C.F.R. § 59.5(a)(5) (2019).[2] Similarly, it provides that "[a] Title X project may not encourage, promote or advocate abortion as a method of family planning." § 59.16(a)(1). And "[a] Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion." § 59.14(a). The Final Rule does not define what it means to "encourage," "promote," or "support" abortions. Nor does it fully illuminate the lines between permissible provision of information and impermissible encouragement, promotion, and support.

However, when a Title X client is confirmed to be pregnant, the Final Rule requires that the client "shall be referred to a health care provider for medically necessary prenatal health care." § 59.14(b)(1). Such referral is mandated even if the client has decided not to carry the pregnancy to term. The "Title X provider may"—but is not required to—provide "[n]ondirective pregnancy counseling." *Id.* That counseling can only be "provided by physicians or advanced practice providers [("APPs")]," *id.*, defined as "a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients," § 59.2. As a result, medical professionals without a graduate level degree, such as registered nurses or licensed practical nurses, cannot provide such counseling.

The Final Rule forbids Title X grantees from making referrals for abortion services. *See* § 59.5(a)(5) (A Title X project "must . . . . [n]ot provide, promote, refer for, or support abortion as a method of family planning."); § 59.14(a) ("A Title X project may not . . . refer for . . . abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion."). Even if a client specifically requests a referral to an abortion provider, the Title X project can at most provide "[a] list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care)." § 59.14(b)(1)(ii), (c)(2). The list cannot include specialty clinics that do not also provide comprehensive primary health care. Further, the referral list "may be limited to those that do not provide abortion." § 59.14(c)(2). If the referral list includes abortion providers, those providers may not comprise "the majority" of the providers

[2] Unless otherwise indicated, all citations in the form of "§ ___" are to the Final Rule published at 84 Fed. Reg. at 7786–91.

on the list, and "[n]either the list nor project staff may identify which providers on the list perform abortion." *Id.* Hence, a Title X project may provide a client seeking an abortion a referral list of only providers who do not perform abortions without so indicating. A Title X project responding to a client's request for an abortion referral can, at most, provide a list on which more than half of the providers do not provide abortions. And the project cannot tell the patient which of the providers actually performs abortions. With respect to medical emergencies, the Final Rule states: "In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency." § 59.14(b)(2). The Final Rule provides as the single example of a qualifying emergency "an ectopic pregnancy." § 59.14(e)(2).

These counseling and referral restrictions represent a sharp break from the 2000 regulations, as well as the prior 1981 guidelines effective since 1993. Until now, Title X grantees have been required[3] to offer pregnant women nondirective pregnancy counseling and referral upon request. 42 C.F.R. § 59.5(a)(5). Grantees were not required to refer a woman who did not intend to continue her pregnancy to prenatal care, and no restrictions were placed on referral lists.

2. Requirement of Physical and Financial Separation

Under the Final Rule, "[a] Title X project must be organized so that it is physically and financially separate . . . from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 of these regulations from inclusion in the Title X program." § 59.15. "In order to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities," and "[m]ere bookkeeping separation of Title X funds from other monies is not sufficient." *Id.* The Secretary will determine whether such objective integrity and independence exist by looking to relevant factors that include: "The existence of separate, accurate accounting records"; "[t]he degree of separation [of] facilities (*e.g.*, treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites)"; "[t]he existence of separate

[3] An exception is made for grantees with moral and religious objections to abortion. *See* 76 Fed. Reg. 9968 (2011).

personnel, electronic or paper-based health care records, and workstations"; and the "extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent." *Id.*

The new separation requirements again represent a marked departure from the current rule. Under the 2000 regulations, grantees' abortion activities were required to be financially separate from their Title X activities, but "[c]ertain kinds of shared facilities [we]re permissible, so long as it [wa]s possible to distinguish between the Title X supported activities and non-Title X abortion-related activities." 65 Fed. Reg. at 41281. For example, common waiting rooms and staff were permissible, as long as the costs and salaries were properly pro-rated and allocated. *Id.*

3. Removal of Requirement that Family Planning Methods and Services be "Medically Approved"

Previous Title X regulations required projects to "[p]rovide a broad range of acceptable and effective *medically approved* family planning methods . . . and services." 42 C.F.R. § 59.5(a)(1) (2000) (emphasis added). The Final Rule removes the "medically approved" language; it simply requires Title X projects to "[p]rovide a broad range of acceptable and effective family planning methods . . . and services." § 59.5(a)(1).

4. Encouragement of Family Participation

The Final Rule requires Title X grantees to "[e]ncourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged)." § 59.5(a)(14).

The 2000 regulations contained no such requirement, although Title X itself provides that "[t]o the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection." 42 U.S.C. § 300(a).

C. Procedural Background

The motions currently before the Court arise from two lawsuits. The first is brought by the State of California ("California"). *See State of California v. Azar et al.*, No. 3:19-cv-1184-EMC (N.D. Cal. filed March 4, 2019) ("*California*"), Docket No. 1 ¶ 1. The second is brought by

Essential Access Health, Inc. and Dr. Melissa Marshall (collectively, "Essential Access"). *See Essential Access Health, Inc., et al. v. Azar et al.*, No. 3:19-cv-1195-EMC (N.D. Cal. filed March 4, 2019) ("*Essential Access*"), Docket No. 1 ¶¶ 15–16. California's Title X network is the largest in the nation. *California* Docket No. 1 ¶ 3. Essential Access is a nonprofit corporation that is California's sole Title X grantee and administers the state's Title X program. *Essential Access* Docket No. 1 ¶ 15. Dr. Marshall is the Chief Executive Officer of CommuniCare Health Centers in Yolo County, California, which has been part of the State's Title X network since 1993. *Id.* ¶ 16. California, Essential Access Health, and Dr. Marshall are hereinafter referred to collectively as "Plaintiffs." Defendants are HHS and Alex M. Azar, II, sued in his official capacity as Secretary of HHS.

California and Essential Access filed their respective motions for preliminary injunction on March 21, 2019. *California* Docket No. 26 ("California Mot."); *Essential Access* Docket No. 25 ("Essential Mot."). Defendants filed a consolidated opposition on April 8, 2019. *California* Docket No. 61 ("Opp."). Plaintiffs filed replies on April 11, 2019. *California* Docket No. 84 ("California Reply"); *Essential Access* Docket No. 63 ("Essential Reply"). The Court held a hearing on the motions on April 18, 2019.

II. LEGAL STANDARD

A preliminary injunction is a matter of equitable discretion and "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Its "purpose . . . is to preserve the status quo and the rights of the parties until a final judgment issues in the cause." *U.S. Philips Corp. v. KBC Bank N.V.*, 590 F.3d 1091, 1094 (9th Cir. 2010).

A party seeking a preliminary injunction must meet one of two variants of the same standard. The traditional *Winter* standard requires the movant to show "that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20. Under the "sliding scale" variant of the same standard, "if a plaintiff can only show that there are 'serious questions going to the merits'—a lesser showing than likelihood of

success on the merits—then a preliminary injunction may still issue if the 'balance of hardships tips *sharply* in the plaintiff's favor,' and the other two *Winter* factors are satisfied." *All. for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017) (emphasis in original) (quoting *Shell Offshore, Inc. v. Greenpeace, Inc.*, 709 F.3d 1281, 1291 (9th Cir. 2013)). In other words, irrespective of the robustness of the showing on the merits required, a plaintiff must demonstrate it is likely to suffer irreparable injury in the absence of preliminary relief. Accordingly, the Court begins by addressing that factor.

III. DISCUSSION

A. Likelihood of Irreparable Harm, the Balance of Equities, and the Public Interest

The record evidence establishes that the irreparable injury, balance of hardships, and public interest factors tip sharply in Plaintiffs' favor. *All. for the Wild Rockies*, 865 F.3d at 1217.

1. Harm to California's Public Health and Essential Access's Organizational Mission

Plaintiffs are likely to suffer several forms of irreparable harm unless the Final Rule is enjoined pending resolution of this case on the merits. The first type of harm is to California's public health and to Essential Access's organizational mission to promote access to high-quality healthcare. *See State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1074 (N.D. Cal. 2018) (finding irreparable harm from agency rule that "will have irreparable consequences for public health") (citing *Sierra Club v. U.S. Dep't of Agric., Rural Utilities Serv.*, 841 F. Supp. 2d 349, 358–59 (D.D.C. 2012)); *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013) (finding irreparable harm where "organizational plaintiffs have shown ongoing harms to their organizational missions as a result of the statute"); *League of Women Voters of United States v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (holding that obstacles that "make it more difficult for the [organizations] to accomplish their primary mission . . . provide injury for purposes both of standing and irreparable harm").

California's efforts to advance its public health objectives by "provid[ing] women and men a means by which they decide for themselves the number, timing, and spacing of their children," Cantwell Decl. ¶ 3, and Essential Access's mission "to champion and promote quality sexual and reproductive health care for all," Rabinovitz Decl. ¶ 3, are in accord. Both will be undermined by

the Final Rule qualitatively and quantitatively.

First, the Final Rule will directly compromise providers' ability to deliver effective care and force them to obstruct and delay patients with pressing medical needs. Abortion is a time-sensitive procedure; the medical risks and costs associated with it "increase with any delay." Kost Decl. ¶ 93. Yet, the Final Rule erects barrier after barrier between patients trying to make an informed decision about whether to continue their pregnancies and their clinicians. A clinician *must* refer a pregnant patient to prenatal care that focuses on carrying the pregnancy to term, even if the patient has made clear her decision to terminate her pregnancy. *Id.* ¶¶ 87, 91. The clinician *cannot* refer the patient to a provider of abortion services, even if the patient specifically requests such a referral. *Id.* ¶ 88. At most the clinician may provide a referral list. Most of the list must be non-abortion providers—in other words, most of the list must be *non-responsive* to what the patient requests. *Id.* And the clinician is *barred* from even identifying to the patient which providers on the referral list are the ones she asked for (providers of abortion services), so the patient must expend further time and effort figuring out for herself which providers on the list in fact can give her the care she wants and needs. *Id.* Incredibly, the Final Rule does not require a clinician who furnishes a patient with a referral list that is wholly non-responsive to even *notify her that the list does not contain a single provider of the services she requested*. *Id.* This pregnancy counseling process is thus, as the President of Essential Access aptly puts it, a "charade" from beginning to end. Rabinovitz Decl. ¶ 50. The overall effect of the Final Rule is to "harm and confuse all patients" during a medically and emotionally sensitive period and "ultimately threaten their health and well-being." Kost Decl. ¶¶ 90, 92, 94.

Second, the Final Rule threatens to drastically reduce access to the wide array of services provided by Title X projects by driving large numbers of providers out of the program. Compliance with the physical separation requirement, which in many cases effectively requires providers to establish "mirror" facilities and staff, would be cost-prohibitive for many providers in California's Title X network. *See* Rabinovitz Decl. ¶ 43; Nestor Decl. ¶ 13; McKinney Decl. ¶ 10; Forer Decl. ¶ 31. In addition, a significant number of Title X projects have indicated that they will likely drop out of the program because they believe the Final Rule compels them to compromise

the quality of care they provide and violate their ethical obligations. Sub-recipients of Essential Access's Title X funds representing 233 clinic sites serving over 774,000 patients "would leave or consider leaving" Title X if they are prohibited from referring patients for abortion services. Rabinovitz Decl. ¶ 42. Sub-recipients representing 194 clinic sites serving over 682,000 patients "will leave or consider leaving" if they are required by the Final Rule to encourage family involvement where an adolescent patient seeks confidential services. *Id.*; *see, e.g.*, Nestor Decl. ¶¶ 11–12; McKinney Decl. ¶ 9. Likewise, "Planned Parenthood affiliates and their health centers"—which serve over 40% of all Title X patients nationwide—"would be forced to discontinue their participation in Title X if the Proposed Rule takes effect." Rich Decl., Exh. M at 15–16.

The net effect of so many providers leaving Title X will be a significant reduction in the availability of important medical services. The substantial Title X funding Essential Access currently receives—approximately $20 million per year—provides "comprehensive sexual and reproductive health care for more than 1 million" patients in California annually. Rabinovitz Decl. ¶¶ 1, 13–15. Essential Access has submitted evidence that the vast majority of its sub-recipients—85 percent—would be forced to lay off staff, cut training, and reduce outreach and education activities without that funding. *Id.* ¶ 44. A third would have to reduce clinic hours. *Id.* Some would have to shut down core services and programs entirely. *See, e.g.*, Thomas Decl. ¶¶ 11–13 (Fresno Economic Opportunities Commission "will not be able to operate" HEARTT, its family planning and reproductive health service for youth, without Title X funds); Nestor Decl. ¶¶ 5–10, 14 (Without Title X funds, the San Francisco Department of Public Health will have to "substantially curtail" its training programs, public education and outreach projects, and "special projects to address emerging public health challenges"); Marshall Decl. ¶ 28 ("Without Title X funding, CommuniCare will not run the outreach services that inform young people of its teen clinic services, nor provide teen clinic services at all."); Wilburn Decl. ¶¶ 16–21, ("The loss of Title X funds will be nearly fatal to [the Community Action Partnership of San Luis Obispo County]'s Health and Prevention Division," including its outreach programs, teen program, and Hepatitis C testing services).

If Title X funding is reduced, patients in California accordingly stand to lose access to a

wide range of "vital health services," many of which have nothing to do with abortion, since Title X providers "serve as a trusted entry point for medical care generally." California Mot. at 24; *see, e.g.*, Rabinovitz Decl. ¶ 12 ("In 2017 alone, Essential Access sub-recipients . . . provided more than 1.6 million family planning visits" and administered "more than 148,000 Pap tests, more than 118,000 clinical breast exams, more than 642,000 chlamydia screenings, more than 700,000 gonorrhea screenings, and more than 341,000 HIV tests."); Brindis Decl. ¶¶ 59–60; Tuttle Decl. ¶ 8; McCarthy Decl. ¶ 7; Wilburn Decl. ¶¶ 17–19. In particular, "[i]n less populous regions, the Rule will create 'contraceptive deserts' where women in need of Title X-funded contraceptive services will be unable to find an affordable, well-qualified provider within their county." California Mot. at 21. Nationwide, in one-fifth of U.S. counties the only safety-net family planning center is a Title X site. Kost Decl. ¶ 78. Should any of these sites drop out of the Title X program as a result of the Final Rule, many individuals would have no access to high-quality, affordable family planning care in their counties at all. *Id.* In California specifically, eighteen counties would be left without a single Title X-funded health center if all the family planning providers that perform abortions were to close. Rabinovitz Decl. ¶ 43.

Even among providers who remain in Title X, service capacity will decrease because the requirement that pregnancy counseling can only be provided by physicians and APPs excludes "vast numbers of medical professionals" who currently provide such counseling. Rabinovitz Decl. ¶ 52; McKinney Decl. ¶ 11; Kost Decl. ¶ 86. This will compound an already "severe crisis in physician and nurse practitioner availability," creating even more critical shortages in counseling resources. Castellano-Garcia Decl. ¶ 11. Many Title X grantees do not have enough physicians and APPs on staff to serve their patients, so those patients will have to either wait for much longer to receive counseling that is often time-sensitive, or simply will not receive the family-planning information they need. *See, e.g.*, McKinney Decl. ¶ 11; Forer Decl. ¶ 30.

Third, the quality of Title X services will be compromised. Patients served by Title X-funded providers use more effective contraceptive methods at higher rates than those served by non-Title X-funded providers. Rabinovitz Decl. ¶ 46. Title X patients "are more likely [than non-Title X patients] to adopt or continue using long-acting and reversible contraceptive methods

('LARCs')," which "are highly effective [in preventing pregnancy] because they obviate the need for daily administration or use at the time of intercourse." *Id.*; *see also* Kost Decl. ¶¶ 119–121 (describing a 35 percent reduction in women using LARCs after Texas "made a series of changes to its family planning program . . . , which included disqualifying agencies providing abortion"). "Diminishing access to LARCs may result in a greater number of unintended pregnancies." Rabinovitz Decl. ¶ 46. Moreover, the Final Rule's separation provision requires health centers to maintain duplicate records systems. Such non-integrated records systems threaten patient health by increasing the risk of error due to "incomplete medical histories, missing data, lost test results, incorrect medication, dosage instructions, and allergy warnings, and other miscommunications across patient records." *Id.* ¶ 70.

Ultimately, the consequence of the reduced availability and quality of health services is worse health outcomes for patients and the public as a whole. The number of unintended pregnancies will increase, which is "likely to result in premature births, low birth weight infants, and congenital defects." Cantwell Decl. ¶¶ 24, 29; Brindis Decl. ¶¶ 52–55. Indeed, the Final Rule could have the perverse effect of *increasing* abortion rates, since "[o]ver half of unintended pregnancies end in miscarriage or abortion." California Mot. at 23; Tosh Decl. ¶ 25 (citing report documenting that 45% of unintended pregnancies result in abortion, and another 13% result in miscarriages). Instances of STIs and other conditions that would otherwise be diagnosed by Title X-funded testing will also likely increase. *See* Brindis Decl. ¶¶ 59–65 (citing study estimating that in 2017, Title X-funded testing "averted approximately 90 to 400 cases of HIV and 47,740 to 56,670 other STIs," diagnosed "many pelvic inflammatory disease (PID) cases, ectopic pregnancies, . . . infertility cases" and "reproductive cancers"); Kost Decl. ¶ 82.

In short, there is substantial evidence in the record before the Court which establishes that California's public health and Essential Access's mission to promote quality sexual and reproductive care will be irreparably harmed unless the Final Rule is enjoined.

2. Economic Harm to California

Next, the economic harms that flow from the Final Rule's detrimental effects on public health also constitute irreparable harm to California. *See California v. Health & Human Servs.*,

351 F. Supp. 3d 1267, 1297 (N.D. Cal. 2019) (*"HHS"*) (finding irreparable harm to plaintiff states where HHS rule creating exemptions to the ACA contraceptive mandate will cause "tens of thousands of women" to lose contraceptive coverage, and the states "document[ed] the fiscal harm that will flow to them as a result"); *see also California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) ("*Azar"*) (affirming finding of irreparable economic harm to states from the same HHS rules "because the states will not be able to recover monetary damages" for their APA claims per 5 U.S.C. § 702).

California's state Medicaid program, Medi-Cal, "is the primary funder for low-income Californians' healthcare services." Cantwell Decl. ¶ 28. Via Medi-Cal, the Final Rule's impact on public health translates to substantial financial and administrative burdens for California. For example, Medi-Cal insures 64% of unplanned births in the state. Tosh Decl. ¶¶ 26, 44. It is estimated that each unintended pregnancy in California costs the public fisc $6,557 in medical, welfare, and other social service costs. *Id.* ¶ 27. Moreover, Medi-Cal "would likely also bear a portion of the costs associated with any delays in the diagnosis and treatment of STIs or breast or cervical cancer." Cantwell Decl. ¶ 30.

3. Economic Harm to Essential Access

Essential Access will also suffer irreparable economic harm if the Final Rule's physical separation requirement becomes effective. Because that requirement is so stringent, Essential Access estimates that it "will be forced to spend exorbitant sums to construct a 'mirror' office," at the cost of $325,000 in the first year and $212,500 every year thereafter. Essential Reply at 13; Rabinovitz Decl. ¶ 66. Its sub-recipients estimate that compliance with the separation requirement will cost an average of $119,000 per agency. Rabinovitz Decl. ¶ 69. Bringing its infrastructure into compliance with the separation requirement will also require Essential Access to divert resources it "otherwise devotes to its core operations and its mission." Essential Mot. at 32 (citing Rabinovitz Decl. ¶ 67); *see E. Bay Sanctuary Covenant v. Trump*, 354 F. Supp. 3d 1094, 1116 (N.D. Cal. 2018) (holding that organizational plaintiffs "'have established a likelihood of irreparable harm' based on their showing of serious 'ongoing harms to their organizational missions,' including diversion of resources") (quoting *Valle del Sol*, 732 F.3d at 1029). As with

the economic harm to California, Essential Access's economic harm is irreparable because it "will not be able to recover monetary damages" for its APA claims. *Azar*, 911 F.3d at 581 (citing 5 U.S.C. § 702)).

4. Defendants' Responses to Plaintiffs' Evidence of Irreparable Harm

Defendants attack Plaintiffs' assertions of irreparable harm on several grounds.

First, Defendants do not dispute that damage to public health can constitute irreparable harm, but instead claim that the public health impact California is describing depends on the response of regulated third parties—*i.e.*, recipients of Title X funding—to the Final Rule, and therefore that the "chain of events necessary to create these speculative harms" is too "attenuated." Opp. at 43 (citing *Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 562 (1992)). Not so.

To begin with, Defendants ignore that the Final Rule's harm to Title X patients described above directly undermines California's public health objectives. Moreover, uncontroverted record evidence Plaintiffs have submitted shows that the harms they describe are not speculative; they are "*likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original). As detailed above, Planned Parenthood has stated unequivocally that its whole network of health centers "would be forced to discontinue their participation in Title X if the Proposed Rule takes effect." Rich Decl., Exh. M at 15. So have many Title X providers in California's network. *See, e.g.*, Nestor Decl. ¶ 11; McKinney Decl. ¶ 9. Indeed, one has already dropped out of Title X as of April 4, 2019 in response to the Final Rule. *Essential Access* Docket No. 64 (Supplemental Rabinovitz Decl.) ¶ 5. Hundreds more have indicated that they "would leave or consider leaving" Title X if the Final Rule is implemented. Rabinovitz Decl. ¶ 42.

Equally unambiguous are the adverse health consequences that will follow from the mass departure of Title X providers. The inverse correlation between the availability of publicly-funded contraceptives and the rate of unintended pregnancies is well-documented in the record. *See* Brindis Decl., Exh. B at 11, 12 n.73 (citing a 2015 report showing that 286,700 unintended pregnancies were averted in California in a single year as a result of publicly funded contraceptive services); Rich Decl., Exh. L at 31–32 ("Title X-funded services helped women avert an estimated 822,300 unintended pregnancies in 2015 alone, thus preventing 387,200 unplanned births and

277,800 abortions. Without services provided by these providers, the U.S. unintended pregnancy rate would have been 31% higher."). Plaintiffs have also cited three case studies documenting the adverse health consequences that directly resulted when family planning services providers that offer abortion-related services were excluded from public funding. *See* Brindis Decl., Exh. B at 6–7 (Indiana county that cut funding to Planned Parenthood facility almost immediately experienced "one of the largest and most rapid HIV outbreaks the country has ever seen"); Kost Decl. ¶¶ 119–22 (disqualifying agencies that provided abortion services from public funding in Texas and Iowa led to marked decreases in family planning services rendered and the use of effective contraceptives).

Moreover, there is already a "severe" shortage of physician and nurse practitioner availability, so implementation of the Final Rule's physician and APP requirement will directly exacerbate patients' lack of access to pregnancy counseling. Castellano-Garcia Decl. ¶ 11; McKinney Decl. ¶ 11; Forer Decl. ¶ 30. The resulting shortfall in service capacity caused would manifest immediately, before any final decision on the merits in this case will be reached. *See* 11A Charles Alan Wright et al., Federal Practice and Procedure § 2948.1 (3d ed. 2013) ("Perhaps the single most important prerequisite for the issuance of a preliminary injunction is a demonstration that if it is not granted the applicant is likely to suffer irreparable harm before a decision on the merits can be rendered."). Nothing about this chain of causation is attenuated.

What *is* speculative is Defendants' assurance that any gap left by an exodus in current Title X providers will be fully filled by new providers entering the program. Defendants point to HHS's claim in the Final Rule that it "does not anticipate that there will be a decrease in the overall number of facilities offering [Title X] services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." 84 Fed. Reg. at 7782; *see also id.* at 7756. But this claim is not backed by any discernible evidence or analysis.[4] *See* Part III.C.2.f., *infra* (discussing HHS's analysis of the expected costs and benefits

[4] Given the lack of evidence that new grantees will enter the Title X program, it is hardly surprising that Defendants do not appear to have considered how much time it would take these hypothetical new grantees to become operational Title X providers, and what the impact on

of the Final Rule). In fact, at oral argument, when pressed for any record evidence substantiating this (highly consequential) assertion, Defendants' counsel could offer none. Counsel insisted that it is "just intuitive" that new grantees will fully replace departing ones in the "fluid marketplace" for medical services. Intuition is no rebuttal to Plaintiffs' evidence of threatened irreparable harm. Nor is Defendants' "intuition" presumed as a matter of logic and common sense. Plaintiffs note that nationwide, in one-fifth of U.S. counties, including rural counties in California, the only safety-net family planning center is a Title X site. Kost Decl. ¶ 78; *see also* Rabinovitz Decl. ¶ 51 (stating that in some rural areas of California, a patient would have to travel more than five hours in order to access an abortion provider that qualifies for a referral under the Final Rule). It defies common sense to assume that in these regions, new healthcare centers will simply materialize and seamlessly assume the client load of exiting grantees.

Second, Defendants insist that the claimed harm to Essential Access is not imminent. Opp. at 43–44. This argument is unavailing for the same reason that the expected harm to California is not speculative—Plaintiffs' evidence demonstrates that access to and the quality of family planning services will be adversely affected as soon as the Final Rule goes into effect. With respect to compliance costs, the process for establishing a physically and financially separate "mirror" office would "requir[e] Essential Access to expend resources on planning and implantation of operational changes *immediately* after the Final Rule takes effect."[5] Rabinovitz Decl. ¶ 66 (emphasis added); *see id.* ¶ 68. The same time pressure extends to Essential Access's sub-recipients. McKinney Decl. ¶ 10. Furthermore, as to Essential Access' ability to deliver quality health care, it cannot be ignored that abortion is a time-sensitive procedure, and the medical risks and costs associated with it "increase with any delay." Kost Decl. ¶ 93; *cf. Chalk v. U.S. Dist. Court Cent. Dist. of California*, 840 F.2d 701, 710 (9th Cir. 1988) (finding that time-sensitive nature of AIDS diagnosis is a "factor favoring a preliminary injunction"). The Final

patients might be from even a temporary disruption in services.

[5] The Final Rule sets a compliance date for the physical separation requirement of March 4, 2020. 84 Fed. Reg. at 7791. But of course, grantees will have to begin the process for bringing their operations into compliance far before that.

Rule, by requiring Title X projects to provide incomplete and perhaps even misleading information to patients, and prohibiting projects from referring patients to abortion providers, forces patients to expend more time and effort to secure information and referrals regarding abortions. In doing so, it increases the health risks and limits the care options for pregnant women, whether they have already decided to obtain an abortion or are simply seeking more information to guide their determination of whether to continue their pregnancies. *See* Kost Decl. ¶ 94 ("[T]he inability to make a fully informed decision on how to proceed with a pregnancy would be especially harmful for women with severe diabetes, heart conditions, HIV/AIDS and estrogen-dependent tumors—all conditions that could be exacerbated by continuing a pregnancy."). In other words, the Final Rule is likely to jeopardizing patients' welfare as soon as it is implemented, thus impairing both patient health and Essential Access' central mission.

Third, Defendants argue that the alleged harm to Essential Access's sub-recipients and Title X patients is not harm to Essential Access itself. *See* Opp. at 43. This argument misses the point. As noted above, Essential Access's organizational mission is to "promote quality sexual and reproductive health care for all." Rabinovitz Decl. ¶ 3. It works toward this mission in part by distributing Title X funds to its sub-recipients to facilitate their provision of family planning services to patients. *Id.* ¶ 6. Thus, the potentially detrimental impact the Final Rule will have on those sub-recipients' capacities to provide services to Title X patients is just one manifestation of the harm that Essential Access will suffer with respect to its organizational mission.

Fourth, Defendants recite the proposition that "ordinary compliance costs are typically insufficient to constitute irreparable harm." Opp. at 45 (quoting *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005)). "But as the Ninth Circuit recently reiterated, the general rule that '[e]conomic harm is not normally considered irreparable' does not apply where there is no adequate remedy to recover those damages, such as in APA cases." *E. Bay Sanctuary Covenant,* 354 F. Supp. 3d at 1116 (quoting *Azar,* 911 F.3d at 581). In *East Bay Sanctuary*, the court found that the plaintiffs established a likelihood of irreparable harm "based on their showing of serious 'ongoing harms to their organizational missions,' including diversion of resources and the non-speculative loss of substantial funding from other sources." 354 F. Supp. 3d at 1116

(citing *Valle del Sol*, 732 F.3d at 1029). The same reasoning obtains here, because Essential Access and its sub-recipients will not be able to recover for the substantial costs they would need to expend to come into compliance with the new separation requirements even if the Final Rule is found to violate the APA.

Accordingly, Plaintiffs have satisfied the irreparable harm prong of the preliminary injunction inquiry.

B. The Balance of Equities and the Public Interest

Where the government is a party to a case in which a preliminary injunction is sought, the balance of the equities and public interest factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Here, both factors weigh in favor of preliminarily enjoining the Final Rule.

On Plaintiffs' side is their interest in averting the "potentially dire public health and fiscal consequences from the implementation of the Final Rules," *HHS*, 351 F. Supp. 3d at 1298, discussed above. The Final Rule threatens to impair the health and welfare of women who benefit from Title X-funded services and Plaintiffs' mission to provide quality healthcare. Moreover, there are the "substantial costs stemming from a higher rate of unintended pregnancies that are likely to occur if women lose access to the [family planning] coverage afforded under the rules now in place." *Id.* And Plaintiffs are not the only ones that will suffer hardship absent an injunction. *See Golden Gate Rest. Ass'n v. City & Cty. of San Francisco*, 512 F.3d 1112, 1126 (9th Cir. 2008) ("In considering the public interest, we may consider the hardship to all individuals covered by the [challenged law], not limited to parties . . . ."). As explained above, public health problems will adversely impact the general public. *See Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1139 (9th Cir. 2009) ("The 'general public has an interest in the health' of state residents.") (quoting *Golden Gate Rest. Ass'n*, 512 F.3d at 1126). A group of thirteen municipalities has also submitted an amicus brief explaining that they will be harmed by the Final Rule in analogous ways to California by the implementation of the Final Rule. *See Essential Access* Docket No. 62 at 7–13. Each of these municipalities receives substantial Title X funding annually and they collectively serve hundreds of thousands of patients through their Title X programs. *See id.* at 4–

7.

On the other hand, Defendants identify no substantiated harm if a preliminary injunction were to issue. They have not documented any substantial abuse of Title X funds. *See* Part III.C.2.b., *infra*. The only harm Defendants currently assert is that which the government will suffer "if it 'is enjoined by a court from effectuating statutes enacted by representatives of its people." Opp. at 46 (quoting *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers)). But as Judge Gilliam pointed out in another case: "Here, of course, the 'representatives of the people'—the United States Congress—passed the [relevant statute], and the precise question in this case is whether the Executive's attempt to implement the Final Rules is inconsistent with Congress's directives." *HHS*, 351 F. Supp. 3d at 1299. As set forth in detail below, this Court finds a high likelihood that the Final Rule was promulgated in violation of substantive statutory law and APA-mandated procedures, and "[t]here is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (citations omitted). "To the contrary, there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" *Id.* (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). It may be true that Defendants intend the Final Rule to represent the government's "value judgment favoring childbirth over abortion," Opp. at 46 (quoting *Rust*, 500 U.S. at 192–93), but that value judgment cannot be effectuated in an unlawful manner or in violation of other Congressional directives.

Hence, the balance of hardships and the public interest tip sharply in favor of Plaintiffs. Although injunctive relief is thus warranted "if [Plaintiffs] can only show that there are 'serious questions going to the merits,'" *All. for the Wild Rockies*, 865 F.3d at 1217, for the reasons discussed below, Plaintiffs have done more than show "serious questions." They have established they are likely to succeed on the merits of many of their claims.

C. Likelihood of Success on the Merits/Serious Questions Going to the Merits

California argues that it is likely to succeed on its APA claims because the Final Rule is not in accordance with law and exceeds statutory authority, in violation of 5 U.S.C. § 706(2)(A)

and (2)(C). California also contends the Rule is arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A).[6] California Mot. at 10–19. Essential Access makes similar arguments under the APA, as well as an additional contention that the Final Rule was promulgated without proper notice and comment. Essential Mot. at 9–21. It also presses two constitutional claims: that the Final Rule infringes upon Dr. Marshall's First Amendment rights, and that it is void for vagueness under the Fifth Amendment Due Process Clause. *Id.* at 21–25. Each claim is addressed below.

1. The Final Rule is Not in Accordance with Law

The APA requires a reviewing court to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "'[N]ot in accordance with law' . . . means, of course, *any* law, and not merely those laws that the agency itself is charged with administering." *F.C.C. v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003) (emphasis in original). Defendants assert that the Final Rule cannot be unlawful under § 706(2)(A) because it is "materially indistinguishable from [the 1988 rule] the Supreme Court has already upheld" in *Rust*. Opp. at 8. Plaintiffs, however, rely on HHS Appropriations Acts and the ACA, which were enacted after *Rust* was decided, so their claim is not automatically foreclosed by *Rust*. The Court therefore must determine whether the Final Rule is inconsistent with the Appropriations Acts and the ACA.

a. The Nondirective Counseling Provision

The most recent "Department of Defense and Labor, Health and Human Services, and Education Appropriations Act" provides:

> For carrying out the program under title X of the PHS Act to provide for voluntary family planning projects, $286,479,000: *Provided*, That amounts provided to said projects under such title shall not be expended for abortions, *that all pregnancy counseling shall be nondirective*, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

[6] California's complaint also alleges that the Final Rule denies women equal protection of the laws in violation of the Fifth Amendment. *See California* Docket No. 1 ¶¶ 221–29. However, California does not rely on that claim in its preliminary injunction motion.

Pub. L. No. 115-245, Div. B, Tit. II, 132 Stat 2981, 3070–71 (2018) (emphasis added). This "Nondirective Counseling Provision" has been included in HHS appropriations acts ("Appropriations Acts") every year since 1996 in substantially similar form. *See, e.g.*, Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321, 1321–22 (1996) (requiring that "all pregnancy counseling shall be nondirective . . . .").

According to Plaintiffs, the provisions of the Final Rule that restrict abortion counseling and referral conflict with the Nondirective Counseling Provision. *See* California Mot. at 11–12; Essential Mot. at 13–14. Defendants in their briefing initially took this to mean that Plaintiffs were arguing that "the nondirective provision implicitly repealed section 1008 and *Rust*," Opp. at 14, because *Rust* upheld similar provisions in the 1988 regulations as a permissible construction of Section 1008. However, Defendants subsequently recognized that the doctrine of implied repeal is not apposite here because the Nondirective Counseling Provision and Section 1008 are not in irreconcilable conflict. *See Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 154–55 (1976) (explaining that repeals by implication come into play "where provisions in the two acts are in irreconcilable conflict") (citation omitted); Opp. at 16 ("There is no conflict—much less an irreconcilable one—between Title X . . . and the nondirective provision."). *Rust* did not purport to interpret Section 1008 as requiring directive counseling in favor of birth; rather, it held that HHS's 1988 rule was one permissible interpretation, not the only permissible interpretation. *See Rust*, 500 U.S. at 184 ("The language of § 1008—that '[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning'—does not speak directly to the issues of counseling, referral, advocacy, or program integrity."). Indeed, at oral argument, Defendants' counsel agreed with Plaintiffs that Section 1008 and the Nondirective Counseling Provision can be read in harmony—requiring pregnancy counseling under Title X to be nondirective does not necessarily run afoul of Section 1008's general proscription that no Title X funds "shall be used in programs where abortion is a method of family planning." That is demonstrated by HHS's 2000 regulations, which proscribed funding of abortions but permitted

nondirective pregnancy counseling.[7]

The question is whether the Final Rule, as one interpretation of Section 1008, is inconsistent with the Appropriations Acts' mandate that "pregnancy counseling" be "nondirective." HHS does not dispute that it has an obligation to comply with the Nondirective Counseling Provision. It wrote in the notice of proposed rulemaking for the Final Rule that "[s]ince it originally created the Title X program in 1970, Congress has, from time to time, imposed additional requirements on it," including "the annual Title X appropriation includes the provisos that 'all pregnancy counseling shall be nondirective.'" 83 Fed. Reg. 25502, 25502 (2018) ("Proposed Rule"); *id.* at 25507 n.11 ("That counseling on abortion be nondirective is required by the appropriations law applicable to Title X."). Similarly, the Final Rule states that Title X "projects *must* comply with Congress's requirement that pregnancy counseling be nondirective, and the Department *must* enforce that requirement." 84 Fed. Reg. at 7747 (emphases added).

As Defendants see it, however, the Final Rule is not inconsistent with the Nondirective Counseling Provision because § 59.14(b)(1) of the Final Rule allows a Title X provider to "choose to provide . . . [n]ondirective pregnancy counseling" to a pregnant patient. Plaintiffs contend, on the other hand, that the Final Rule is inconsistent with the Nondirective Counseling Provision because it mandates referrals to prenatal care while categorically barring referrals for "abortion as a method of family planning," and imposes unreasonable restrictions on the provision of referral lists for patients seeking an abortion. Plaintiffs also argue that even without the referral prohibition and restrictions, the Final Rule "effectively prohibits nondirective counseling . . . by issuing a vague prohibition on providers who 'encourage' or 'promote' abortion." California Mot. at 11. Plaintiffs believe this "unclear guidance will likely cause providers to forgo discussions altogether for fear of violating the Rule." *Id.* at 12.

i. "Nondirective Counseling" Includes Referrals

The first part of the parties' dispute focuses on whether "nondirective counseling" under

[7] Apart from the brief period when the 1988 regulations were effective, HHS has consistently interpreted Section 1008 to allow nondirective pregnancy counseling.

the Appropriations Acts encompasses referrals. It does, as indicated by statute, regulations, and industry practice. First, Congress expressed its understanding in the PHSA that "nondirective counseling" includes referral. *See* 42 U.S.C. § 254c-6(a)(1)[8] (providing that HHS shall make training grants "providing adoption information *and referrals* to pregnant women on an equal basis with all other courses of action *included in nondirective counseling* to pregnant women") (emphases added). The PHSA and the HHS Appropriations Acts appear to be the only instances in which Congress has used the term "nondirective counseling," and Defendants have not argued otherwise. Notably, the Final Rule, in interpreting Title X, incorporates the definition of "nondirective counseling" from § 254c-6(a)(1) of the PHSA in the context of adoption. 84 Fed. Reg. at 7733 ("Congress has expressed its intent that postconception adoption information and *referrals be included as part of any nondirective counseling* in Title X projects when it passed [§ 254c-6(a)(1)]") (emphasis added). Congress' use of the identical term "nondirective counseling" should be read consistently across the PHSA and the HHS Appropriations Acts to include referrals as part of counseling. *See Dir., OWCP v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130 (1995) (teaching that, in interpreting an ambiguous statutory phrase, "[i]t is particularly illuminating to compare" two different statutes employing the "virtually identical" phrase); *cf. Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972) ("[A] legislative body generally uses a particular word with a consistent meaning in a given context.").

Second, as a matter of regulatory law, HHS itself characterizes referrals as part of counseling throughout the Final Rule. *See id.* at 7730 ("[N]ondirective pregnancy counseling can include counseling on adoption, and corresponding referrals to adoption agencies."); 7733–34 ("Title X providers may provide adoption counseling, information, and referral as a voluntary family planning service for non-pregnant clients . . . as part of nondirective postconception counseling . . . ."). The Final Rule, in this regard, is not unique. As early as 1981, HHS has defined counseling in its Title X Guidelines to include referral. *See* U.S. Dep't of Health and

[8] Section 254c-6(a)(1) was enacted in 2000, four years after the Nondirective Counseling Provision was first enacted. As noted above, the Nondirective Counseling Provision has been included in every HHS Appropriations Act since 1996, including from 2000 to 2019.

Human Services, *Program Guidelines for Project Grants for Family Planning Services* § 8.2 (1981) ("Post-examination *counseling* should be provided to assure that the client . . . receives appropriate *referral* for additional services as needed.") (emphases added).

Third, the accepted usage within the medical field of "nondirective counseling" supports Plaintiffs' position. *See Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 357 (1986) (articulating "the rule of construction that technical terms of art should be interpreted by reference to the trade or industry to which they apply") (citing *Corning Glass Works v. Brennan*, 417 U.S. 188, 201–02 (1974)); *Alabama Power Co. v. EPA*, 40 F.3d 450, 454 (D.C. Cir. 1994) ("[W]here Congress has used technical words or terms of art, it is proper to explain them by referring to the art or science to which they are appropriate."). This is reflected in the HHS Office of Population Affairs' ("OPA") own "Quality Family Planning" guidelines ("QFP Guidelines"), which are incorporated into the agency's Title X Family Planning Guidelines.[9] *See* Center for Disease Control and Prevention, Providing Quality Family Planning Services (2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf; Rich Decl., Exh. A at 5. The "Pregnancy Testing and Counseling" section of the QFP Guidelines instructs that "[pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals."[10] Brindis Decl., Exh. C at 13–14. The QFP Guidelines then advise that "[o]ptions counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG [the American College of Obstetricians and Gynecologists] and AAP [the American Academy of Pediatrics]." *Id.* at 14. "Both ACOG and AAP are explicit in their recommendations

[9] The OPA website continues to refer providers of family planning services to these guidelines. *See* HHS Office of Population Affairs, Quality Family Planning, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html (last visited April 2, 2019) ("The QFP provide recommendations for use by all reproductive health and primary care providers with patients who are in need of services related to preventing or for achieving pregnancy.").

[10] Understanding referral to be a part of the counseling process also conforms to common sense. A patient would presumably be rather taken aback if, for instance, upon receiving an initial diagnosis of cancer from her doctor, the doctor then refuses to provide a referral for further testing and medically appropriate treatment.

that all pregnant individuals, including adolescents, be provided with factual, nondirective pregnancy options counseling that includes information on and timely referral for abortion services." Kost Decl. ¶ 25. The American Medical Association's comment letter to the Proposed Rule likewise states unequivocally that "[t]he inability to counsel patients about all of their options in the event of a pregnancy and to provide any and all appropriate referrals, including for abortion services, are contrary to the AMA's Code of Medical Ethics." Rich Decl., Exh. I at 3. *See also* Rabinovitz Decl. ¶ 33 ("Nondirective counseling . . . requires nondirective referrals for particular services—including abortion—upon request of the patient.").

That Congress intended "nondirective counseling" include nondirective "referrals" is reinforced by the fact that Congress repeatedly enacted the Nondirective Counseling Provision in substantially the same form every year since 1996. Throughout these last 23 years the HHS regulations have consistently interpreted Title X to "require[], in the event of an unplanned pregnancy and where the patient requests such action, [grantees] to provide nondirective counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects." 58 Fed. Reg. at 7464. "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) (citations omitted); *see Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1154–55 (9th Cir. 2010).

Defendants counter by relying on general dictionary definitions to urge that "'[c]ounseling' does not, in its common usage, necessarily include within its definition the act of 'referral.'" Opp. at 17 (quoting Black's Law Dictionary (10th ed. 2014)). But the Court need not resort to indications of common usage because there is ample statutory, regulatory, and industry guidance on the meaning of "counseling" in the specific context of medical services at issue here. *See United States v. Lettiere*, 640 F.3d 1271, 1274 (9th Cir. 2011) ("Only in the absence of a statutory definition does this court normally look to the ordinary meaning or dictionary definition of a term."); *see also United States v. Costello*, 666 F.3d 1040, 1044 (7th Cir. 2012) (cautioning that "[d]ictionary definitions are acontextual, whereas the meaning of sentences depends critically on context, including all sorts of background understandings").

Next, Defendants point to various instances in the Final Rule where the phrase "counseling and referral" is used. *See, e.g.*, 84 Fed. Reg. at 7730 ("[T]he Department believes that Title X providers can provide certain counseling and referrals in a postconception setting . . . ."), 7747 ("Nondirective counseling and referrals for postconception services . . . are the appropriate approach in the context of pregnancy . . . ."), 7778 ("[T]he final rule eliminates the requirement that Title X projects provide abortion counseling and referral."). To Defendants, the conjunction "and" indicates that counseling and referral are discrete activities. Absent any other interpretive guidance, this may be a plausible reading. But given the express references to counseling as "including" referral in the PHSA, elsewhere in HHS regulations, and in the Final Rules, the phrase "counseling and referral" occasionally used by HHS is more sensibly read as simply describing sequential aspects of the same process.

Finally, Defendants cite a 1992 bill that expressly sought to "reverse[] the regulations issued in 1988 and upheld by the Supreme Court in 1991 to restrict the provision of information on abortion to Title-Ten patients." Opp. at 17 (quoting H.R Rep. No. 102-204, at 1 (1991)). The bill, which was passed by Congress but vetoed by President George H. W. Bush, defined "pregnancy management options" to mean "nondirective counseling and referrals." S. 323, 102nd Cong. § 2 (1992). Defendants contend that Congress' later enactment of the Nondirective Counseling Provision *without* specific mention of "referral" as in the 1992 bill signifies that Congress intended to exclude referral from the scope of nondirective counseling mandated by the subsequent Appropriations Acts. *See* Opp. at 18. This argument ignores important context. The 1992 bill was introduced in the immediate wake of and as an explicit response to the *Rust* decision. Because *Rust* upheld the 1988 regulations that expressly banned abortion counseling and referrals, it is not surprising that Congress felt the need to specify in explicit terms that it was putting both abortion-related counseling and referral back on the table. But by the time Congress enacted the Nondirective Counseling Provision in 1996, the pre-1988 regulatory scheme that treated abortion referrals as a part of counseling had already been restored. *See* 58 Fed. Reg. 7462. Since 1993, the HHS regulations have permitted abortion referrals. This obviated the need for the Nondirective Counseling Provision to make explicit reference to both counseling and

referral.

Although Defendants invoke the proposition that "[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language," *United States v. Novak*, 476 F.3d 1041, 1071 (9th Cir. 2007), it is hazardous to apply this principle to divine the intent of a Congress that passed the Nondirective Counseling Provision four years after the vetoed 1992 bill given the different historical contexts of the 1992 bill and the subsequent 1996 Appropriations Act. *See Cohen v. United States*, 650 F.3d 717, 730 (D.C. Cir. 2011) ("[I]t is the enacted text rather than the unenacted legislative history that prevails.") (citation omitted). Defendants cite nothing in the legislative history suggesting that Congress in 1996 considered, and rejected, a version of the Nondirective Counseling Provision that expressly required abortion referral or that Congress otherwise intended to exclude referrals from the provision.

In sum, the Court finds that the statutory language, PHSA, Title X regulations, and usage within the medical field all indicate that nondirective counseling includes nondirective referrals.

ii. The Final Rule's Referral Restrictions Violate the Nondirective Counseling Provision

Applying this definition, sections 59.14(a), 59.14(b)(1), and 59.14(c)(2) of the Final Rule likely violate the Nondirective Counseling Provision. "Nondirective pregnancy counseling is the meaningful presentation of options where the [medical professional] is not suggesting or advising one option over another." 84 Fed. Reg. at 7716; *see* 42 U.S.C. § 254c-6(a)(1) (providing that nondirective pregnancy counseling involves "providing adoption information and referrals to pregnant women on an equal basis with all other courses of action"). To be nondirective, the medical professional must "present[] the options in a factual, objective, and unbiased manner and . . . rather than present[] the options in a subjective or coercive manner." 84 Fed. Reg. at 7747.

The categorical prohibition on providing referrals for abortion in § 59.14(a) is not nondirective because it prevents Title X projects from presenting abortion on an equal basis with

other pregnancy options.[11] In contrast to § 59.14(a), § 59.14(b)(1) mandates that every pregnant patient be referred to "prenatal health care," even a patient who has expressly stated that she does not want prenatal care. This differential treatment is not "nondirective." The mandate compels providers to present the options in a coercive manner and pushes patients to pursue one option over another; it does not allow "clients [to] take an active role in processing their experiences and identifying the direction of the interaction." 84 Fed. Reg. at 7716. Indeed, Defendants conceded at oral argument that if referral is considered a part of counseling, § 59.14(b)(1) violates the Nondirective Counseling Provision.

Defendants also acknowledged that the referral list restrictions in § 59.14(c)(2) stand and fall together with the prohibition on abortion referrals in § 59.14(a). Section 59.14(c)(2) allows Title X projects to provide a client with a referral list "limited to those that do not provide abortion," even if the client specifically requests an abortion referral. It further prevents projects from providing a referral list on which "the majority" of the providers perform abortion services, and from "identify[ing] which providers on the list perform abortion." Far from meaningfully presenting a patient with her medical options, such a "non-referral referral list" (as Plaintiffs' counsel labels it) is likely to cause confusion and delay in her attempt to obtain care. The patient would have to spend time working through the list to determine which referrals actually provide the services she asked for—time she may not have given the time-sensitive nature of decisions about pregnancy and related care. Imposing these onerous restrictions only on abortion information does not place abortion on an equal basis with all other courses of action.

iii. The Final Rule's Counseling Restrictions Violate the Nondirective Counseling Provision Apart From Referrals

There is also merit to Plaintiffs' contention that, the referral prohibition aside, the Final Rule one-sidedly chills counseling regarding abortion. Sections 59.5(a)(5) and 59.14(a) bar providers from doing anything to "promote" or "support" abortion. *See also* § 59.16(a)(1) ("A

[11] The overlapping prohibition on abortion referrals in § 59.5(a)(5) violates the Nondirective Counseling Provision for the same reason. *See* § 59.5(a)(5) (Title X projects may "[n]ot provide, promote, refer for, or support abortion as a method of family planning.").

Title X project may not encourage, promote or advocate abortion as a method of family planning."). At oral argument, Defendants' counsel struggled to draw a clear boundary between mentioning or describing abortion as a pregnancy option within the permissible scope of nondirective counseling and "promoting" or "supporting" abortion impermissible under §§ 59.5(a)(5) and 59.14(a). Essentially, counsel was only able to offer a circular definition: A provider can avoid "promoting" or "supporting" abortion by counseling nondirectively, and a provider can counsel nondirectively by not "promoting" or "supporting" abortion. This interpretive murkiness is telling. It suggests that providers desiring to explain the abortion option have to walk on eggshells to avoid a potential transgression of the Final Rule, whereas those describing the option of continuing the pregnancy face no comparable risk. This lack of symmetry created by §§ 59.5(a)(5) and 59.14(a) is likely to chill discussions of abortion and thus inhibits neutral and unbiased counseling.

Accordingly, Plaintiffs have established a likelihood of success on the merits of their claim that sections 59.14(a), 59.14(b)(1), and 59.14(c)(2) violate the Nondirective Counseling Provision of the Appropriations Acts and are thus not in accordance with law.

b. Section 1554 of the ACA

Plaintiffs next argue that the Final Rule violates Section 1554 of the ACA. *See* California Mot. at 12–13; Essential Mot. at 10–13. Section 1554 provides:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that–
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or

(6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

i. Defendants' Threshold Arguments Do Not Foreclose Plaintiffs' Section 1554 Claim

Before proceedings to the merits of Plaintiffs' Section 1554 claim, the Court first addresses several threshold issues raised by Defendants.

(a) Plaintiffs' Section 1554 Claim Has Not Been Waived

First, Defendants argue that Plaintiffs have waived any challenge based on Section 1554 because they did not raise the issue with HHS during the notice and comment period. Opp. at 19. It is a "general rule" that courts "will not review challenges to agency action raised for the first time on appeal." *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1023 (9th Cir. 2007) (citing *Exxon Mobil Corp. v. E.P.A.*, 217 F.3d 1246, 1249 (9th Cir. 2000)). Parties may thus "waive[] their right to judicial review" of arguments "not made before the administrative agency" or "in the comment to the proposed rule." *Exxon Mobil*, 217 F.3d at 1249. Plaintiffs concede that neither they nor any other commenter specifically notified HHS during the comment period that the Proposed Rule may violate Section 1554. However, they assert that numerous commenters stated that the Final Rule violated the ACA, and therefore that HHS was "provided sufficient notice . . . to afford it the opportunity to rectify the [Section 1554] violations that the plaintiffs alleged." *Native Ecosystems v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002). Plaintiffs compiled these comments in a supplemental submission to the Court. *See California* Docket No. 97.

In reviewing whether these comments are sufficient to overcome waiver, the Court heeds the Ninth Circuit's guidance that "the exhaustion requirement should be interpreted broadly." *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010). "Plaintiffs need not state their claims in precise legal terms, and need only raise an issue 'with sufficient clarity to allow the decision maker to understand and rule on the issue raised.'" *Id.* (quoting *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 968 (9th Cir. 2006)).

Applying this permissive standard, the Court finds that, although it is a close call, Plaintiffs

have raised at least a serious question as to whether their Section 1554 claim has been adequately exhausted. The record suggests that commenters raised issues pertaining to Section 1554 with sufficient clarity to provide notice to HHS. Several comments specifically contend the Final Rule violates the ACA. *See, e.g., California* Docket No. 97 ¶ 2 ("The proposed definition of what would be considered a 'medically approved' family planning method . . . would effectively limit access and coverage of reproductive health choices expanded upon in the ACA . . . ."), ¶ 4 (This proposed change is . . . contrary to the Affordable Care Act . . . .").

In themselves, these comments may not be specific enough to suggest that the Final Rule violates any specific provision of the ACA. But they were complemented by numerous comments using identical or substantially identical language to Section 1554 to describe how the Final Rule would impede access to care. *Compare, e.g.,* § 1554(1) (". . . creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care"), *with California* Docket No. 97 ¶ 6 ("The Proposed Rule seeks to create barriers to access to women's healthcare, including abortion.") *and* ¶ 7 (The Proposed Rule "would create barriers to access for an even larger number of women nationwide."); § 1554(2) (". . . impedes timely access to health care services"), *with California* Docket No. 97 ¶ 14 (The Proposed Rule "would prevent Title X providers from sharing complete and accurate medical information necessary to ensure that their patients are able to . . . obtain timely care.") *and* ¶ 17 ("This proposed gag on providers will prevent patients from accessing health care in a timely manner."); § 1554(3) (". . . interferes with communications regarding a full range of treatment options between the patient and the provider"), *with California* Docket No. 97 ¶ 20 ("The NPRM would ban Title X providers from giving women full information about their health care options.") *and* ¶ 22 ("The proposed rule limits how Title X providers can discuss and/or counsel on the full-range of sexual and reproductive health care options with their patients."); § 1554(4) (". . . restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions"), *with California* Docket No. 97 ¶ 25 (The Final Rule "undermines the right to information by censoring health care providers from informing patients of all their options related to abortion.").

The comments raising concerns regarding medical ethics and informed consent per §

1554(5) are particularly specific. *Compare* § 1554(5) (". . . violates the principles of informed consent and the ethical standards of health care professionals"), *with California* Docket No. 97 ¶ 26 ("The Proposed Rule requires physicians to disregard their Code of Medical Ethics . . . ."), ¶ 27 ("The Proposed Rule directly conflicts with the recommendations of major medical professional associations, including the American College of Obstetricians and Gynecologists and the American College of Physicians . . . ."), ¶ 31 ("[T]he rule's proposed ban on abortion referral and its chilling effect (or possibly an effective ban) on abortion counseling are repudiations of ethical and professional standards around informed consent . . . ."). The terms "ethical standards" and "informed consent" are commonly understood within the medical field to refer to established standards, including those published by the American College of Physicians ("ACP") and the American College of Obstetricians and Gynecologists ("ACOG"). HHS has long referenced these ethical standards in connection with Title X, including throughout its QFP Guidelines. *See, e.g.*, QFP Guidelines at 13; 65 Fed. Reg. at 41273–74.

To be sure, these comments did not explicitly reference Section 1554, but the Ninth Circuit has repeatedly emphasized that commenters "need not state their claims in precise legal terms" to exhaust them, *Nat'l Parks*, 606 F.3d at 1065, and "alerting the agency in general terms will be enough if the agency has been given a chance to bring its expertise to bear to resolve the claim," *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) (citation and alteration omitted). *See, e.g.*, *Oregon Nat. Desert Ass'n v. McDaniel*, 751 F. Supp. 2d 1151, 1165 (D. Or. 2011) (finding no waiver where plaintiff raised the issue underlying its Wilderness Act claim by complaining to the agency that its action would harm "500,000 acres of recommended future wilderness," "even though it never actually invoked the Wilderness Act before the agency"); *Sierra Forest Legacy v. U.S. Forest Serv.*, 652 F. Supp. 2d 1065, 1081 (N.D. Cal. 2009). And here, HHS acknowledged that it had received many comments objecting that the Final Rule created barriers to patients' access to care, interfered with provider-patient communications, and violated principles of medical ethics, and addressed them (albeit unsatisfactorily, *see* Part III.C.2., *infra*). *See, e.g.*, 84 Fed. Reg. at 7722–24, 7745 (acknowledging comments regarding barriers to access to care and medical ethics).

That HHS dismissed the concerns raised in these comments, which were couched in the same terms as Section 1554's prohibitions, indicates that the commenters "raise[d] [the] issue with sufficient clarity to allow the decision maker to understand and rule on the issue raised," *Nat'l Parks*, 606 F.3d at 1065, and that the agency's response would likely have been no different even if the commenters had specifically cited Section 1554.[12] *See Native Ecosystems*, 304 F.3d at 899 (holding that where "the administrative decisionmaker understood plaintiffs to raise the issue" and "addressed this concern in its decision," there is no waiver); *Nat. Res. Def. Council v. E.P.A.*, 755 F.3d 1010, 1023 (D.C. Cir. 2014) (holding that an issue "expressly addressed by" the agency "is properly before the court").

Accordingly, the Court concludes that Plaintiffs have raised a serious question that their Section 1554 claim was not waived.

(b) Section 1554 Limits the Secretary's Authority under Title X

Second, Defendants argue that Section 1554 does not affect the scope of HHS's rulemaking authority under Title X. Defendants reason that the prefatory language in Section 1554, "[n]otwithstanding any other provision of this Act," limits the scope of Section 1554 to the ACA. 42 U.S.C. § 18114. According to Defendants, if Congress had intended for Section 1554 to sweep more broadly beyond the ACA, it could have written the statute to say, "notwithstanding any other provision of law." Opp. at 21–22.

However, the plain text of Section 1554 does not limit its application to the ACA. "Notwithstanding any other provision of this Act" simply means that the Secretary cannot engage in the type of rulemaking proscribed by Section 1554 even if another provision of the ACA could be construed to permit it—the directive of Section 1554 is to be given primacy. This meaning is underscored by the expansive second clause of Section 1554: "the Secretary of Health and Human Services shall not promulgate *any regulation* . . . ." 42 U.S.C. § 18114 (emphasis added). The literal text of Section 1554 does not support Defendants' construction.

That Section 1554 has application beyond the ACA is neither surprising nor unusual;

[12] Notably, HHS specifically discussed Section 1554 in a concurrent rulemaking. *See* 83 Fed. Reg. 57536, 57551–52 (2018).

surrounding provisions do too. *See, e.g.*, 42 U.S.C. § 18116(a) (nondiscrimination provision that extends to all federally-funded health programs). Moreover, where Congress wanted a provision to apply only to the ACA, it said so explicitly. For example, Section 1553 directs that "[t]he Federal Government, and any State or local government or health care provider that *receives Federal financial assistance under this Act* . . . may not subject an individual or institutional health care entity to discrimination . . . ." 42 U.S.C. § 18113(a) (emphasis added). Similarly, Section 1555 provides that "[n]o individual, company, business, nonprofit entity, or health insurance issuer offering group or individual health insurance coverage shall be required to participate in any Federal health insurance program *created under this Act*." 42 U.S.C. § 18115 (emphasis added). The "clear" and "express" language in these sections limiting their applicability to the ACA demonstrates that "Congress knows how to limit the [statute] when it wishes to do so." *Miller v. Clinton*, 687 F.3d 1332, 1340 (D.C. Cir. 2012). Congress did not use such express language in Section 1554.

Defendants invoke two other principles of statutory interpretation to argue that Section 1554 does not apply to Title X. Neither advances Defendants' cause. The first is the "principle that Congress 'does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.'" Opp. at 20 (quoting *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001)). In Defendants' telling, it is implausible that Congress would have "abrogated a Supreme Court decision on an *extremely* controversial subject"—*Rust*—by means of an ancillary ACA provision. *Id.* (emphasis in original). But this account is fundamentally flawed because when the ACA was enacted in 2010, the counseling and referral restrictions in *Rust* had long been rescinded, so Section 1554 was entirely consistent with the prevailing Title X regulatory scheme. And as noted above, *Rust* merely upheld one interpretation of Title X; it did not purport to definitively interpret Title X itself. Thus, Section 1554, to the extent it bars the "gag rule," would not abrogate Section 1008.

The second principle is that "the specific [statute] governs the general." Opp. at 22 (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)). Defendants assert that Section 1008, as a specific prohibition on funding abortion as a method of family planning within

Title X, trumps the more general Section 1554. *See id.* at 23. This "canon is impotent, however, unless the compared statutes are 'irreconcilably conflicting.'" *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 698–99 (D.C. Cir. 2014) (citation omitted). For the reasons just discussed, Section 1008 and Section 1554 are not irreconcilably conflicting. And Defendants recognize as much. *See* Opp. at 21. The former forbids the use of Title X funds "in programs where abortion is a method of family planning," 42 U.S.C. § 300a-6, whereas the latter limits HHS's authority to promulgate any regulation which violates the principles of informed consent and ethical standards of medical professionals, *id.* § 18114. These "two statutes are capable of co-existence." *Morton*, 417 U.S. at 551. The pre-Final Rule regulatory scheme gives effect to both. It prevents impermissible use of Title X funds by enforcing financial separation between projects that receive Title X funding and projects that perform services prohibited under Section 1008. At the same time, it permits Title X projects to give patients nondirective counseling and referrals to abortion service providers upon request, in compliance with Section 1554(5).

Because there is no "irreconcilable conflict" between the two statutes, Defendants' contention that Plaintiffs' claim relies on the premise that Section 1554 impliedly repealed Section 1008 is likewise inapposite. *See* Opp. at 20; *Radzanower*, 426 U.S. at 154–55 (one statute can be found to have impliedly repealed another "where provisions in the two acts are in irreconcilable conflict").

(c) Section 1554 is Not Unreviewably Broad

Third, Defendants suggest that Section 1554 is so "open-ended" that "it is a substantial question whether section 1554 claims are reviewable under the APA at all." Opp. at 22. Defendants cite *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971) for the proposition that there are times when "statutes are drawn in such broad terms that in a given case there is no law to apply," frustrating judicial review. *Id.* at 410. But *Overton Park* made clear that this is "a very narrow exception" to the APA only to be applied in "rare instances." *Id.* This is not one of those rare instances. Other, arguably more open-ended statutory commands have been held to permit judicial review. *See, e.g.*, *Morgan Stanley Capital Group Inc. v. Pub. Util. Dist. No. 1 of Snohomish County*, 554 U.S. 527, (2008) (wholesale electricity rates must be "just and

reasonable"); *Pac. Nw. Generating Co-op. v. Bonneville Power Admin.*, 596 F.3d 1065, 1077 (9th Cir. 2010) (agency must operate "consistent with sound business principles"); *City of Los Angeles v. U.S. Dep't. of Commerce*, 307 F.3d 859, 869 n.6 (9th Cir. 2002) (Secretary of Commerce must use statistical sampling "if he considers it feasible"); *Keating v. FAA*, 610 F.2d 611, 612 (9th Cir. 1979) (agency must make decision "in the public interest"). Section 1554 is not a statute "drawn so that the court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

(d) The Constitutional Reasoning in *Rust* Does Not Foreclose Plaintiffs' Section 1554 Claim

Finally, Defendants, citing reasoning from *Rust*, made a further suggestion at oral argument that Plaintiffs' Section 1554 claim is meritless because, even if the Final Rule impeded patients' access to care, "[t]he difficulty that a woman encounters when a Title X project does not provide abortion counseling or referral leaves her in no different position than she would have been if the Government had not enacted Title X." *Rust*, 500 U.S. at 202. This belated challenge is both legally and factually misguided.

As a legal matter, Defendants are importing language from *Rust*'s constitutional holding in an attempt to extinguish Plaintiffs' statutory claim. The *Rust* Court decided that the 1988 regulations did not impermissibly burden a woman's Fifth Amendment right to choose whether to terminate her pregnancy because "Congress' refusal to fund abortion counseling and advocacy leaves a pregnant woman with the same choices as if the Government had chosen not to fund family-planning services at all." *Id.* It was in this context of evaluating a constitutional claim that the Court reasoned the regulations left patients no worse off than if Title X did not exist. *See id.* By contrast, Plaintiffs' claim here is that the Final Rule violates a specific statutory prohibition. The statutory mandates of Section 1554 are far more specific than the constitutional requirement asserted in *Rust*. The claim under Section 1554 is a matter of statutory interpretation to which *Rust* is inapposite.

Moreover, as a factual matter, the Final Rule's referral list restrictions go far beyond anything in the 1988 regulations. The new restrictions: (1) permit a Title X project to give a

patient who *specifically requests* a referral for abortion a referral list that contains *no* abortion providers; (2) require the project to compile a list of providers, a majority of whom are *not* responsive to the patient's request; (3) prevents the project from identifying which providers on the list *are* responsive to the patient's needs; and (4) *does not require the project to even alert the patient that the list is incomplete and non-responsive*. *See* § 59.14(c)(2). Because of these provisions, patients in need of time-sensitive medical care will be delayed or altogether prevented from obtaining that care because they will receive referrals that they do not realize are not for the services they requested. *See* Rich Decl., Exh. K at 2. In other words, under the Final Rule, the Government would be subsidizing the misdirection of unsuspecting patients. Unlike in *Rust*, the Final Rule may well make patients *worse* off than if they had not sought help from a Title X project to begin with.[13]

ii. The Final Rule Violates Section 1554

Having found that Plaintiffs' claim under Section 1554 is not foreclosed, the Court must determine whether the Final Rule in fact violates that provision of the ACA. Plaintiffs assert that the Final Rule's restrictions on counseling and referral and requirement for providers to encourage family participation in family planning decisions are contrary to Section 1554. The Court agrees.

The Court has already detailed extensively the ways in which the Final Rule's overlapping restrictions on pregnancy counseling (including referral and referral lists) obfuscate and obstruct patients from receiving information and treatment for their pressing medical needs. *See* Parts III.A.1 and III.C.1.a., *supra*; Kost Decl. ¶¶ 88–93; Rabinovitz Decl. ¶ 50; Marshall Decl. ¶ 22. There is no question that these restrictions "create[] . . . unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impede[] timely access to health care services," "interfere[] with communications regarding a full range of treatment options between the patient

[13] After it received commenters' objections that the referral restrictions "will deprive women of the information they need about abortion or where to obtain one," HHS offered a rather astonishing response: "[I]n the Department's view, it is not necessary for women's health that the federal government use the Title X program to . . . give to women who seek abortion the names of abortion providers. Information about abortion and abortion providers is *widely available and easily accessible, including on the internet*." 84 Fed. Reg. at 7746 (emphasis added). The Court does not share Defendants' belief that misleading counseling provided by a medical professional is rendered harmless by information available "on the internet."

and the provider," and "restrict[] the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions" in violation of subparts (1)–(4) of Section 1554. Defendants do not even contest this.

Separately, the Final Rule's prohibition on providing abortion referrals, restrictions on the content of referral lists, and mandate on referrals for prenatal care are also squarely at odds with established ethical standards and therefore Section 1554(5). Indeed, they are inconsistent with HHS's own QFP Guidelines, which provide that once a patient receives a positive pregnancy test:

> Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. Depending upon a client's needs, the provider may make an appointment for the client, or call the referral site to let them know the client was referred.

QFP Guidelines at 14. The QFP Guidelines further instruct that "[p]roviders of family planning services should offer pregnancy testing and counseling services as part of core family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG)." *Id.* at 13. In turn, ACOG explains that physicians have an ethical obligation to "provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner, including raising the child herself, placing the child for adoption, and abortion." Rich Decl., Exh. G at 6.

Clearly, the Final Rule's blanket prohibition on abortion referrals does not comport with providers' ethical obligation to provide "[r]eferral to appropriate providers of follow-up care . . . at the request of the client." QFP Guidelines at 14. And § 59.14(c)(2)'s restrictions that prevent Title X from providing any abortion referrals to a patient who specifically requests such a referral, and from identifying which providers on a referral list perform abortion services, do not "help the client identify options for care." *Id.* Comments in the record show that associations of medical professionals overwhelmingly agree that the Final Rule's counseling and referral restrictions violate principles of medical ethics and informed consent. *See, e.g.*, Rich Decl., Exh. B at 4–5 (California Medical Association stating that restrictions "directly conflict[] with the requirements of medical professional associations, including [ACOG]."); Exh. D at 4 (American Academy of

Nursing stating that restrictions "violate[] basic ethics of the profession," including the Code of Ethics for Nurses); Exh. E at 7 (Guttmacher Institute stating that restrictions "constitute[] an unacceptable repudiation of the doctrine of informed consent by denying Title X patients factual, unbiased information on abortion"); Exh. G at 3–6 (ACOG stating that restrictions violate its Code of Professional Ethics); Exh. I at 3 (American Medical Association stating restrictions "are contrary to the AMA's Code of Medical Ethics"); Exh. K at 2 (American Public Health Association stating that "[t]he gag rule violates core ethical standards"); Exh. N at 3 (American Academy of Pediatrics stating that restrictions "conflict[] with medical practice guidelines, including those of the American Academy of Pediatrics."); Exh. P at 4–5 (American College of Physicians stating that restrictions violate "the ethical principle of respect for patient autonomy"); *see also* Marshall Decl. ¶ 15; Spirtos Decl. ¶ 18; Kost Decl. ¶¶ 84–85.

The requirement in § 59.14(b)(1) that all pregnant Title X clients "shall be referred to a health care provider for medically necessary prenatal health care," even if it goes against a patient's wishes, violates ethical standards. As ACOG explains, this provision "require[s] the provision of counseling, information, and referral for services that the patient has clearly stated she does not wish to receive." Rich Decl., Exh. G at 3, 6.

Moreover, as the American Public Health Association details, § 59.14(b)(1) also violates ethical principles because while it allows Title X providers to abstain from providing nondirective counseling due to moral or religious reasons, "it does not contain any requirement that those providers advise patients of their refusal." Rich Decl., Exh. K at 2. "Therefore, patients will not even know if they are getting complete information." *Id.*

Finally, the Final Rule's "family participation" requirement also violates ethical standards. Title X itself only asks grantees to "encourage family participation" in Title X projects "[t]o the extent practical." 42 U.S.C. § 300(a). But Section 59.5(a)(14) directs Title X grantees to "[e]ncourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged)." There is an exception to the documentation requirement where a provider

"suspects the minor to be the victim of child abuse or incest." § 59.2(1)(i). The American Academy of Pediatrics ("AAP") notes that healthcare professionals already "highly encourage[] the involvement of families in the care of adolescents and young adults as much as possible," and "[a]s a consequence, most adolescents already involve their families in decisions about family planning." Rich Decl., Exh. N at 6. However, the new requirement in the Final Rule for "clinicians to take 'specific actions' to encourage family participation, even after they have learned that this involvement is not practicable," is "contrary to medical ethics." *Id.* AAP explains that "clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not 'practicable,' or unrealistic or even harmful to encourage the minor to involve their parents or guardian." *Id.* In these situations, requiring clinicians to nevertheless encourage family participation and document those efforts would both force them to breach their ethical obligations and "drive some minors away from returning for critical health services."[14] *Id.* Other commenters, including ACOG, echo AAP's conclusion that § 59.5(a)(14) violates medical ethics. *See id.*, Exh. G at 14.

Accordingly, Plaintiffs have demonstrated that they are likely to succeed on the merits of their claim that §§ 59.5(a)(5), 59.5(a)(14), 59.14(a), 59.14(b)(1), 59.14(c)(2), and 59.16(a)(1) of the Final Rule are not in accordance with Section 1554.

2. The Promulgation of the Final Rule was Arbitrary and Capricious

Under the APA, agency action must be set aside if it is arbitrary or capricious. 5 U.S.C. § 706(2)(A). An agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[14] Courts have long recognized that "in matters concerning sexual conduct, minors frequently are reluctant, either because of embarrassment or fear, to inform their parents of medical conditions relating to such conduct, and consequently that there is a considerable risk that minors will postpone or avoid seeking needed medical care if they are required to obtain parental consent before receiving medical care for such conditions." *Am. Acad. of Pediatrics v. Lungren*, 16 Cal. 4th 307, 317–18 (1997); *Ballard v. Anderson*, 4 Cal. 3d 873, 880 (1971) ("[A]n unmarried pregnant minor understandably might be reluctant to seek parental consent for medical care related to her pregnancy and that the parents of such a minor might refuse consent for reasons unrelated to the health of the minor.").

Although "a court is not to substitute its judgment for that of the agency," *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (citation omitted), it nevertheless "retain[s] a role, and an important one, in ensuring that agencies have engaged in reasoned decisionmaking," *Judulang v. Holder*, 565 U.S. 42, 53 (2011).

In particular, an agency which changes its position must give a reasoned explanation for the change. "[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that [an agency] display awareness that it *is* changing position." *Fox Television*, 556 U.S. at 515 (emphasis in original). Typically, the agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better." *Id.* (emphases in original). "This means that the agency need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate." *Id.* But "[s]ometimes it must—when, for example, its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." *Id.* at 515–16. Indeed, "even when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation." *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015).

"Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43.

a. Plaintiffs' Arbitrary and Capricious Claims are Not Foreclosed by *Rust*

Defendants contend Plaintiffs' arbitrary and capricious claims are foreclosed by *Rust*. *See* Opp. at 24–26. This argument is meritless. When it decided *Rust* in 1991, the Supreme Court found that "the Secretary amply justified his change of interpretation [from the pre-1988 regulations] with a 'reasoned analysis,'" based on "critical reports of the General Accounting

Office (GAO) and the Office of the Inspector General (OIG), that prior policy failed to implement properly the statute." *Rust*, 500 U.S. at 187. "He also determined that the new regulations are more in keeping with the original intent of the statute, are justified by client experience under the prior policy, and are supported by a shift in attitude against the 'elimination of unborn children by abortion.'" *Id.*

The justifications supporting the 1988 regulations upheld in *Rust* cannot insulate the Final Rule from review now, almost three decades later. In promulgating the Final Rule, HHS did not purport to rely on the 1988 regulations. *See Michigan v. E.P.A.*, 135 S. Ct. 2699, 2710 (2015) (It is a "foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action." Nor can HHS rely *ipse dixit* on the factual bases justifying the 1988 regulations. *See Sierra Club v. U.S. E.P.A.*, 671 F.3d 955, 966 (9th Cir. 2012) ("[An agency] stands on shaky legal ground relying on significantly outdated data" to justify its actions.). Unlike the 1988 regulations considered in *Rust*, the Final Rule was not enacted in response to critical reports of the GAO and OIG, and makes no mention of negative "client experiences" under the current regulations that have been in effect since 1993. Nor does the Final Rule cite any instances of actual co-mingling or misuse of Title X funds. Accordingly, that *Rust* upheld the 1988 regulations does not dispose of Plaintiffs' APA challenge to the Final Rule here. This Court must conduct the arbitrary and capricious analysis anew.

As another threshold issue, Defendants contended at oral argument that Plaintiffs' arbitrary and capricious claims are foreclosed by the *Chevron* analysis in *Rust*. According to Defendants, the mere fact that the 1988 regulations were a permissible interpretation of Title X alone supplies the reasoned basis HHS needs to justify the Final Rule under the APA. This argument is belied by *Rust* itself. If a reasonable and permissible statutory interpretation was all that was needed for the 1988 regulations to pass muster under arbitrary and capricious review, the Supreme Court would have said so. Although the ambiguous language of Section 1008 and equivalent legislative history of Title X might arguably have sustained the 1988 regulations, as noted above, the Court nevertheless scrutinized the evidentiary basis given for the 1988 regulations to ensure that they were the product of a "reasoned analysis." *Rust*, 500 U.S. at 187.

On this point, Defendants overlook important differences between *Chevron* and arbitrary-and-capricious review. As the Ninth Circuit has delineated, "*Chevron* . . . analyzes the reasonableness of an agency's interpretation [of a statute], while 'arbitrary and capricious' review under the APA focuses on the reasonableness of an agency's decision-making *processes.*" *CHW W. Bay v. Thompson*, 246 F.3d 1218, 1223 (9th Cir. 2001) (emphasis in original) (citation omitted). Here, it is precisely the reasonableness of HHS's decisionmaking process in promulgating the Final Rule that Plaintiffs challenge. Hence, the lens of arbitrary-and-capricious review must be applied. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) ("[W]here a proper challenge is raised to the agency procedures, and those procedures are defective, a court should not accord *Chevron* deference to the agency interpretation."); *New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 324 (2d Cir. 2003) ("When the question is not one of the agency's authority but of the reasonableness of its actions, the 'arbitrary and capricious' standard of the APA governs."). It would be particularly inappropriate to conflate *Chevron* and *State Farm* in this case because, as detailed below, Plaintiffs have persuasively shown that the Final Rule "was issued without the reasoned explanation that was required in light of [HHS]'s change in position and the significant reliance interests involved." *Encino Motorcars*, 136 S. Ct. at 2126.

Accordingly, the Court proceeds to the merits of Plaintiffs' arbitrary and capricious claims to determine whether the Final Rule is supported generally by a reasoned analysis, and in particular to the extent the Final Rule represents a change in position which requires a "more detailed justification," whether HHS sufficiently justified its change in position.

b. The Physical Separation Requirement is Arbitrary and Capricious

Plaintiffs contend the physical separation requirement in § 59.15 is arbitrary and capricious. *See* California Mot. at 17; Essential Mot. at 15–17. The record reveals that Plaintiffs are likely correct. HHS relied on speculative fears of theoretical abuse of Title X funds to justify imposing the physical separation requirement and turned a blind eye to voluminous evidence documenting the significant adverse impact the requirement would have on the Title X network and patient health. The agency's actions fell short of reasoned decisionmaking.

i. Defendants Relied on Speculative Justifications Belied by the Record

The Final Rule cites the following justification for requiring physical separation:

> [S]hared facilities create a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities, and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics. Even with the strictest accounting and charging of expenses, a shared facility greatly increases the risk of confusion and the likelihood that a violation of the Title X prohibition will occur.

84 Fed. Reg. at 7764. Defendants' opposition brief affirms that the physical separation requirement is based on "the need for prophylactic measures to address the risk and the perception that taxpayer funds will be used to fund abortion." Opp. at 30.

Defendants' repeated use of words like "risk," "likelihood," "prophylactic," and "specter" is telling; Defendants fail to point to any evidence in the record of *actual* co-mingling or misuse of Title X funds. HHS primarily relies on two sources to justify its concerns about insufficient separation. The first is an "anecdotal story" from 2007 about a California clinic's community outreach activities. 84 Fed. Reg. at 7774. But this anecdote, by Defendants' own admission, does not actually involve the misuse of Title X funds at all. It is an "example of abuse of federal funds in a *different* program," Medicaid. Opp. at 29 n.3 (emphasis added); *see* 84 Fed. Reg. at 7725 ("The Department agrees with comments stating that demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused . . . ."). The second is a 2014 Guttmacher Institute report indicating that "abortions are increasingly performed at sites that focus primarily on contraceptive and family planning services—sites that could be recipients of Title X funds." 84 Fed. Reg. at 7765. But this report provides no support for HHS's position. By the agency's own interpretation, the report merely shows that abortions are being performed at "sites that *could* be recipients of Title X funds," *id.* (emphasis added); it does not say that those sites actually *are* Title X projects. Even assuming that abortions are being performed at actual Title X sites, there is no basis for concluding that this would constitute a violation of Title X. It is important here to remember the Supreme Court's explanation in *Rust* that

> Title X expressly distinguishes between a Title X *grantee* and a Title X *project.* The grantee, which normally is a health-care organization, may receive funds from a variety of sources for a variety of purposes. The grantee receives Title X funds, however, for the specific and limited purpose of establishing and operating a Title X project. . . . The Title X *grantee* can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct those activities through programs that are separate and independent from the project that receives Title X funds.

500 U.S. at 196 (emphases in original) (citing 42 U.S.C. § 300(a)). Thus, the mere fact that abortions are being performed at the site of a Title X *grantee* does not mean that the Title X *project* operating within the grantee is misusing Title X funds to perform abortions. HHS cites no evidence to contradict its prior finding that financial separation and the concomitant review and rigorous audit of Title X grantees' financial records was a sufficient safeguard. *See* 65 Fed. Reg. at 41275–76.[15]

The evidence HHS cites for its concern about public "perception that Title X funds being used" in relation with prohibited abortion activities, 84 Fed. Reg. at 7764, is equally without a reasoned basis. According to the agency, in response to the Proposed Rule, it received comments from "many commenters that oppose defining 'family planning' to exclude abortion and that urge the Department to define the term to include abortion." *Id.* at 7729. Far from showing that the public erroneously believes Title X funds are being used to fund abortion-related activities, these comments suggest the very opposite—that the commenters understand Title X funds *cannot* currently be used for abortion, but would like HHS to change its definition of "family planning" to include abortion so that Title X funds *can* potentially be used for abortion-related activities.

Defendants advance another argument: they believe that "the collocation of a Title X clinic with an abortion clinic permits the abortion clinic to achieve economies of scale" and therefore "support[s] abortion as a method of family planning" with Title X funds. *Id.*. at 7766. But the notion that any use of Title X funds that might indirectly benefit an abortion clinic is necessarily

[15] To the extent there may have been isolated instances of misuse or co-mingling of Title X funds in the past that were not cited in the Final Rule, there is no indication they escaped detection from the financial audits conducted under the 2000 regulations.

misuse is a radical one that goes far beyond any rationale for physical separation approved in *Rust*. It ignores a pivotal distinction drawn in *Rust*: "Title X expressly distinguishes between a Title X *grantee* and a Title X *project*," and a "Title X *grantee* can continue to . . . provide abortion-related services" so long as it does so "through programs that are separate and independent from the project that receives Title X funds." 500 U.S. at 196 (emphases in original). HHS's sweeping new argument would obliterate the Court's carefully drawn distinction. The limitless reach of the agency's rationale is also "illogical on its own terms." *Am. Fed'n of Gov't Emps., Local 2924 v. Fed. Labor Relations Auth.*, 470 F.3d 375, 380 (D.C. Cir. 2006). A grantee that, pursuant to the Final Rule, maintains separate facilities and medical records between its Title X services and abortion services can still benefit from economies of scale in, for example, rent (if the grantee rents separate spaces within the same building) and medical record system (if the grantee purchases its separate systems from the same vendor). *See id.* (an agency's decision is arbitrary and capricious if "illogical on its own terms"); *Illinois Pub. Telecom. Ass'n v. F.C.C.*, 117 F.3d 555, 566 (D.C. Cir.) (an agency's "seemingly illogical" decision is arbitrary and capricious), *decision clarified on reh'g*, 123 F.3d 693 (D.C. Cir. 1997).

In sum, the asserted fear of misuse of Title X funds purporting to animate HHS's decision to fundamentally depart from its current regulations and impose an onerous physical separation requirement are not substantiated by the record. To the contrary, HHS reported as recently as October 2018 that "family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities, such as abortion." Angela Napili, *Congressional Research Service Report for Congress: Family Planning Program Under Title X of the Public Health Service Act*, at 14 (Oct. 15, 2018), https://fas.org/sgp/crs/misc/R45181.pdf.

Defendants contend they do not need to justify the Final Rule by reference to an extant problem, because "agencies can . . . adopt prophylactic rules to prevent potential problems before they arise." *Stilwell v. Office of Thrift Supervision*, 569 F.3d 514, 519 (D.C. Cir. 2009) (Kavanaugh, J.). However, "[t]hough an agency's predictive judgments about the likely economic effects of a rule are entitled to deference, deference to such judgments must be based on some

logic and evidence, not sheer speculation." *Sorenson Commc'ns Inc. v. F.C.C.*, 755 F.3d 702, 708 (D.C. Cir. 2014) (citations, internal quotation marks and alterations omitted). In *Sorenson Communications*, the D.C. Circuit found arbitrary and capricious a rule providing that the Federal Communications Commission ("FCC") would only reimburse service providers for captioning-enabled phones they sold to hearing-impaired individuals if those phones cost $75 or more. *Id.* at 705. The FCC "claim[ed] the $75 Rule w[ould] deter fraudulent acquisition and use of [captioning-enabled phones]. Yet the agency offer[ed] no evidence suggesting there is fraud to deter." *Id.* at 707. The court faulted the FCC for promulgating the rule without an evidentiary basis, asking, "where is the evidence that [the] technology is being fraudulently used?" *Id.* at 708. The court rejected the FCC's assertion "that it may rely on its predictive judgment to ignore these questions" and concluded that the agency had "failed to articulate a satisfactory explanation for its action" because its claimed fear of fraud was speculative. *Id.* at 708–09; *see also Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 839 (D.C. Cir. 2006) (finding that agency action premised on addressing "a claimed record of abuse" is arbitrary and capricious because the agency "provided no evidence of a real problem" with abuse); *Arizona Cattle Growers' Ass'n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (holding agency action to be arbitrary and capricious where the basis of the action is "speculation . . . not supported by the record.").

Likewise here, HHS purports to rely on its predictive judgment that Title X funds will be misused without the physical separation requirement, but the Final Rule provides no evidence that indicates this projection is anything but speculation. Quite the opposite, the projection is at odds with the agency's repeated assurances from as early as 2000 and as recently as 2018 that the existing separation requirements are sufficient to prevent abuse within the Title X program. Accordingly, HHS has failed to "articulate a satisfactory explanation" for the physical separation requirement as required by the APA, and is thus arbitrary and capricious. *State Farm*, 463 U.S. at 43.

ii. HHS Failed to Provide a "More Detailed Justification" for Its Change in Policy

The arbitrary nature of the change in policy becomes even more clear when HHS's decisionmaking is measured against its obligation to supply "a more detailed justification" for adding the physical separation requirement; a detailed justification is required because its decision relied "upon factual findings that contradict those which underlay its prior policy" and because "its prior policy has engendered serious reliance interests." *Fox Television*, 556 U.S. at 515.

HHS clearly set forth the factual findings underlying its decision in 2000 to rescind the physical separation requirement in the 1988 regulations. It noted, on the one hand, that mandating physical separation conferred no discernible benefits. The agency reasoned that it had "traditionally viewed" financial separation—"demonstrate[d] by [a Title X grantee's] financial records, counseling and service protocols, administrative procedures, and other means"—as sufficient. 65 Fed. Reg. at 41276. And "since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary." *Id.* at 41275. Thus, "it is hard to see what additional statutory protection is afforded by the imposition of a requirement for 'physical' separation." *Id.* at 41276. On the other hand, HHS concluded that a physical separation requirement "is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services." *Id.* The agency took seriously comments objecting that physical separation would be "costly[] and medically unwise." *Id.* at 41275. In particular, requiring separation of staff and facilities would: "be inefficient and cost ineffective," especially "for small and rural clinics that may be the only accessible Title X family planning and/or abortion providers for a large population of low-income women"; be "inconsistent with public health principles, which recommend integrated health care"; and "burden women, by making them make multiple appointments or trips to visit different staff or facilities." *Id.* at 41275–76 (internal quotation marks omitted).

By contrast, in reinstating the physical separation requirement in the Final Rule, HHS stated that "it no longer believes financial separation is sufficient without physical separation." 84

Fed. Reg. at 7764. It also "disagree[d]" with commenters who protested "that the physical and financial separation requirements will destabilize the network of Title X providers" by imposing significant compliance costs. *Id.* at 7766. Instead, the agency "believes that, overall, the final rule will contribute to more clients being served, gaps in services being closed, and improved client care that better focuses on the family planning mission of the Title X program." *Id.* These factual findings upon which the Final Rule rests "contradict those which underlay [HHS's] prior policy." *Fox Television*, 556 U.S. at 515.

The prior separation policy also engendered "serious reliance interests" with respect to regulated entities, including Plaintiffs. Essential Access has detailed the significant investment it has made in its physical infrastructure, programming, and records systems over the years in reliance on the longstanding rule that financial separation between its Title X and non-Title X activities complies with Section 1008. For example, core to Essential Access's mission of promoting quality reproductive care is its training arm, the Learning Exchange, which "trained more than 6,000 clinicians and allied health professionals from forty-nine states on providing quality sexual and reproductive health care" in 2017. Rabinovitz Decl. ¶ 61. Based on the current regulations, the Learning Exchange programming includes "training on pregnancy options, including how to provide patients with medically accurate, unbiased, non-judgmental information about abortion, adoption, and parenting." *Id.* ¶ 62. Similarly, Essential Access provides "extensive" non-Title X-funded public education and awareness programming, reaching over 650,000 adolescents, about comprehensive sexual and reproductive health. *Id.* ¶ 64. The Final Rule would require Essential Access to completely overhaul this programming and reallocate its resources in order to comply with the new requirement that any activities relating to abortion must be conducted "with a separate staff, under a separate roof, using separate workstations, email addresses, and phone numbers." *Id.* ¶ 65. This entails "extraordinary expenses." *Id.* ¶ 66.

Essential Access sub-recipients likewise would need to revamp their "medical record systems and financial records, undertake extensive renovations, and hire new staff and personnel," which are integrated in reliance on the current regulations. *Id.* ¶ 69. *See also* Nestor Decl. ¶¶ 5–6, 13 (San Francisco Department of Public Health uses Title X funds to train its clinical staff

members on "contraceptive counseling" and "pregnancy testing and counseling," but it "cannot bear the cost of setting up separate facilities" and "separate personnel" to bifurcate its Title X and non-Title X services); Forer Decl. ¶¶ 7, 31 (Title X grantee Venice Family Clinic provides "fully integrated primary healthcare services," including family planning services, and it would be "financially impossible for [its] three Title X funded clinic sites to build entirely separate adjoining sites"); McKinney Decl. ¶¶ 8, 10 (Title X grantee Westside Family Health Center, which does not provide abortions but does "provide nondirective pregnancy counseling and referrals for abortion when requested," cannot afford to "rent or purchase separate property to provide non-directive counseling or referrals for abortion services"). As Plaintiffs' counsel explained at oral argument, these investments made in integrated staff and systems mean that a reversal of course by the agency now would engender more costs than would have been incurred if the separation requirement had been in force years ago.

The reliance interests these Title X grantees have demonstrated are similar to those recognized by the Supreme Court as warranting a more detailed explanation of an agency's change in policy. *See Encino Motorcars*, 136 S. Ct. at 2126–27 (holding that automobile dealerships had established "decades of industry reliance" on prior Department of Labor policy exempting dealerships from paying overtime compensation to "service advisors," because "[d]ealerships and service advisors negotiated and structured their compensation plans against this background understanding," and eliminating the exemption "could necessitate systemic, significant changes to the dealerships' compensation arrangements"). Defendants attempt to distinguish *Encino Motorcars* on the basis that it "concerned private parties' substantive statutory rights," where "the challenged regulations here concern discretionary funding decisions" and grants that are "generally available for only one year." Opp. at 31. But courts have recognized serious reliance interests in discretionary grants of benefits that do not arise from statute—in, for example, the Deferred Action for Childhood Arrivals program, a form of time-limited discretionary relief from deportation created by an executive branch memorandum. *See Regents of Univ. of California v. United States Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1022, 1045 (N.D. Cal.), *aff'd sub nom. Regents of the Univ. of California v. U.S. Dep't of Homeland Sec.*, 908 F.3d 476 (9th Cir.

2018); *Nat'l Ass'n for the Advancement of Colored People v. Trump*, 315 F. Supp. 3d 457, 473 (D.D.C. 2018); *Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 431 (E.D.N.Y. 2018). To the extent Defendants suggest that any reliance on the current Title X regulations was unreasonable because agency policy can change at any time, that argument ignores the fact that the type of review described in *Fox Television* was specifically made in the context of a change in an agency's policy, not a statute. As the Court in *Fox Television* explained, one purpose of arbitrary-and-capricious review of agency action is precisely to safeguard reliance interests from being upended by erratic policy shifts by administrative agencies. *See* 556 U.S. at 515. Here, Title X grantees have relied on HHS consistently interpreting Section 1008 to require only financial separation for over a quarter century; that the Supreme Court required a more detailed explanation from an agency changing a policy that had engendered "decades of industry reliance" reflects that regulated entities are justified in structuring their affairs in reliance on longstanding agency policy. *Encino Motorcars*, 136 S. Ct. at 2126.

At bottom, HHS has not demonstrated there are "good reasons" for the physical separation requirement or provided a "more detailed justification' for the change in policy. *Id.*

iii. HHS Failed to Provide Any Explanation for Its Estimates of Compliance Costs

The promulgation of the physical separation requirement is arbitrary and capricious for a second, independent reason. During the notice-and-comment period, commenters provided HHS with substantial evidence that imposing a physical separation requirement on Title X grantees would create significant (and in many cases, prohibitive) compliance costs, drastically reduce access to Title X services, and lead to serious disruptions in care for Title X patients. Instead of engaging with these concerns, HHS summarily dismissed them, maintaining that "overall, the final rule will contribute to more clients being served, gaps in services being closed, and improved client care that better focuses on the family planning mission of the Title X program." 84 Fed. Reg. at 7766. In doing so, the agency "entirely failed to consider an important aspect of the problem" and "offered an explanation for its decision that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

With respect to compliance costs, HHS's analysis at every stage of the rulemaking has been mystifying. Initially, the Proposed Rule "estimate[d] that an average of between $10,000 and $30,000, with a central estimate of $20,000, would be incurred [by each affected Title X site] to come into compliance with physical separation requirements in the first year following publication of a final rule." 83 Fed. Reg. at 25525. In reaching these figures, the agency quoted several costs grantees are likely to incur to "evaluate[] . . . whether they comply with the proposed physical separation requirements." *Id.* But merely *evaluating* the compliance status of a Title X site is only the first of many steps in the process of actually *coming into compliance* with the physical separation requirement. For instance, sites will need to maintain separate accounting and health records, as well as separate physical facilities (including "treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites.)" § 59.15(a)–(c). There is no mention of the costs of complying with these requirements in the Proposed Rule.[16] Also conspicuously absent is any estimate of compliance costs beyond the first year.

Many Title X grantees submitted detailed comments explaining that their compliance costs would be much higher than estimated in the Proposed Rule. Planned Parenthood estimated that just the capital costs of renovation and construction would be "nearly $625,000 per affected service site." Rich Decl., Exh. M at 31–32 (providing extensive calculations). The National Family Planning and Reproductive Health Association wrote that "[i]t would cost hundreds of thousands of dollars or more to locate and open a facility, staff it, purchase separate workstations, set up separate record-keeping systems, etc.," and estimated capital costs of compliance at

[16] HHS's own "Guidelines for Regulatory Impact Analysis" ("HHS Guidelines") set forth in ample detail how the agency should estimate the costs for "[r]egulated entities . . . to comply with regulatory requirements." U.S. Dep't of Health and Human Services, *Guidelines for Regulatory Impact Analysis* at 32 (2016), https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf. These costs explicitly include "purchasing computers and software to support administrative tasks," "installing or retrofitting new equipment," "capital expenditures to acquire buildings or land," and "annual costs of labor, utilities, and other resources." *Id.* at 32–33. The HHS Guidelines teach that "analysts generally use market data to estimate such costs." *Id.* Here, HHS referenced no data, market or otherwise, as the basis for its compliance cost estimates.

$300,000. *Id.*, Exh. L at 37. Commenters further pointed out that the separation requirement would create "significant" ongoing costs, "including contracts for goods and services and staff time," that "the Department fails to acknowledge in the first year and every subsequent year." Rich Decl., Exh. M at 32.

Notwithstanding these comments, the Final Rule changed very little after receiving these comments. HHS revised its central estimate from $20,000 per affected site to $30,000. *See* 84 Fed. Reg. at 7781–82. It criticized the "extremely high cost estimates" provided by commenters as "based on assumptions that they would have to build new facilities in order to comply with the requirements for physical separation." *Id.* at 7781. The agency suggested that "entities will usually choose the lowest cost method to come into compliance," such as "shift[ing] their abortion services, and potentially other services not financed by Title X, to distinct [existing] facilities, a change which likely entails only minor costs." *Id.* This suggestion ignores that commenters had already addressed the possibility of "renovating facilities in order to comply," short of building new ones, and still concluded that renovation costs vastly exceeded the agency's estimates. Rich Decl., Exh. M at 31. Moreover, HHS's claim that shifting existing services "entails only minor costs" is wholly conclusory. Its final estimate of $30,000 per site has no more discernible evidentiary basis than its initial estimate of $20,000—a figure seemingly pulled from thin air—and is an order of magnitude lower than the evidence-backed calculations provided by commenters. Furthermore, HHS also offered no response to commenters' descriptions of their ongoing compliance costs beyond the first year.

HHS also ignored consequential costs of compliance. Numerous commenters explained to HHS that because compliance with the physical separation requirement would be "prohibitive in terms of cost and feasibility" large numbers of Title X providers would be forced to leave the program. Rich Decl., Exh. L at 16–17, Exh. C at 16–17, Exh. G at 11–12, Exh. H at 10–11, Exh. M at 32–34. Plaintiffs have provided ample evidence demonstrating that without Title X funding, these providers would be able to serve far fewer clients, including evidence that Title X funds services for more than 1 million patients in California every year, and that 85 percent of Essential Access subrecipients will have to lay off staff and cut services and programming without Title X

funding. *See* Part III.A.1., *supra*; Rabinovitz Decl. ¶¶ 1, 14–15. The withdrawal of Planned Parenthood alone would create a massive vacuum in services as its health centers currently serve more than 40% of all Title X patients. Rich Decl., Exh. M at 15–16. "[O]ther types of Title X sites would need to increase their client caseloads by 70 percent" just to make up for the shortfall created by Planned Parenthood's departure. *Id.* at 16. "[T]he departure of a large number of Title X-funded providers . . . would reduce access to family planning care with attendant negative impacts on health outcomes and population health. *Id.* at 33. The "adverse health consequences" to patients would include "unintended pregnancies, undetected STDs, and other poor health outcomes." *Id.*; *see id.*, Exh. G at 12–13; U.S. Dep't of Health and Human Services, *Title X Family Planning Annual Report: 2016 National Summary* at 1 (2017) ("For many clients, Title X providers are their only ongoing source of health care and health education."), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf. Further, the physical separation requirement would "force patients to make multiple appointments and trips" for their family planning needs, Rich Decl., Exh. C at 17, creating "unnecessary costs to patients and providers" and "interfer[ing] with the integration of care," *id.*, Exh. M at 33–34. While these costs are more difficult to estimate given their consequential nature, HHS largely ignored these potentially enormous costs.

Instead, in response, HHS cites only a "Christian Medical Association and Freedom2Care poll conducted on May 3, 2011, which found that 91 percent of physicians who practiced medicine based on the principles of their faith said they would be forced to leave medicine if coerced into violating the faith tenets and medical ethics principles that guide their practice of medicine." 84 Fed. Reg. at 7780 n.138. Based on this poll, the agency suggests that "[w]ith the final rule's added emphasis on protecting rights of conscience, more individuals may enter the Title X family planning program, helping to meet that unmet need for care." *Id.* at 7781. The flaws in this leap of logic are myriad. Fundamentally, the poll did not ask doctors anything about Title X specifically. For example, does the permissive ability to provide nondirective abortion counseling and referral actually violate their beliefs? Have the 2000 regulations deterred them from participating in Title X because of their beliefs? Would they join Title X projects if they were not

required to provide nondirective counseling and referral for abortions? More to the point, have these doctors been deterred from joining Title X projects because other projects do not have physically separate facilities? On its face, this would seem to be a non-sequitur. There is particular reason to question the assumption that large numbers of doctors are being discouraged from joining Title X because of their beliefs about abortion because HHS has already implemented rules that, since 2008, have recognized that Title X program requirements must be enforced consistent with federal laws that protect moral and religious conscience. *See* 73 Fed. Reg. 78072 (2008); 76 Fed. Reg. 9968 (2011). In any event, there is no evidence there are enough such would-be doctors who would be prompted by the Final Rule to join Title X to fill the vacuum left by exiting providers. HHS offers no other data or evidence in support of its momentous claim that "the final rule will contribute to more clients being served, gaps in services being closed, and improved client care." 84 Fed. Reg. at 7766.

HHS's conclusory response to commenters' evidence-backed concerns about the serious problems the physical separation requirement will cause flies in the face of established APA principles. *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1186–87 (D.C. Cir. 2004) (holding that courts "do not defer to the agency's conclusory or unsupported suppositions"); *Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 341–42 (D.C. Cir. 1989) (holding that agency's "conclusory statement" dismissing plaintiff's concern that public disclosure of plaintiff's sensitive documents would cause competitive harm was so inadequate as to render the agency's decision "unreviewable"). "[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2707 (2015) (emphasis in original). Here, HHS has "brushed aside critical facts," *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017), and given "no consideration to the disruption" the physical separation requirement would cause, *Regents of Univ. of California v. United States Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1045 (N.D. Cal.), *aff'd*, 908 F.3d 476 (9th Cir. 2018). As such, the promulgation of the physical separation requirement "runs counter to the evidence before the agency" and is arbitrary and capricious under traditional APA principles, *State Farm*, 463 U.S. at 43, and even more so under *Fox Television*,

556 U.S. at 515 (requiring agency to provide a "more detailed justification" for a change in policy and show "that there are good reasons" for the change).

c. The Counseling and Referral Restrictions are Arbitrary and Capricious

Plaintiffs next challenge the promulgation of the Final Rule's restrictions on abortion counseling and referral as arbitrary and capricious. *See* California Mot. at 17–18; Essential Mot. at 17–18.

Defendants' justification for reinstating restrictions on abortion counseling and referrals is that "the 2000 regulations are not consistent with federal conscience laws," including "the Church Amendment, Coats-Snowe Amendment and the Weldon Amendment." 84 Fed. Reg. at 7746; *see* Opp. at 31–32. These conscience laws do not provide a reasoned explanation for the Final Rule's counseling restrictions for two reasons.

First, as noted above, there are already HHS regulations on the books that ensure Title X's implementation is consistent with the conscience laws. In 2008, the agency announced that it "would not enforce [the abortion counseling and referral] requirement on objecting grantees or applicants." 73 Fed. Reg. at 78087. This rule was partially repealed in 2011 and replaced with a "new process for enforcing those [conscience] protections" whereby the HHS Office for Civil Rights addresses any complaints of discrimination under the conscience laws. 76 Fed. Reg. at 9969. The agency emphasized that the "partial rescission of the 2008 Final Rule [in 2011] does not alter or affect the federal statutory health care provider conscience protections." *Id.* HHS fails to explain why a more sweeping set of restrictions is necessary in light of the existing safeguards tailored to ensure Title X's compliance with federal conscience laws. *See Council of Parent Attorneys & Advocates, Inc. v. DeVos*, -- F. Supp. 3d. ---, No. 18-CV-1636 (TSC), 2019 WL 1082162, at *15 (D.D.C. Mar. 7, 2019) (holding that an agency rule is arbitrary and capricious where "the government failed to explain why the [existing] safeguards as a whole would not prevent against the risk" the rule purported to address).

Second, the conscience laws prohibit federal, state, and local governments "from engaging in discrimination against a health care entity on the basis that it does not, among other things, refer for abortion." *Id.* This means HHS may not require Title X grantees to provide abortion referrals

over their objections. But this does not concern grantees which *do not* have moral or religious objections to abortion. The conscience laws do not provide a basis for HHS to bar *all* Title X grantees from providing abortion referrals. Given the lack of a reasoned basis for the counseling and referral restrictions, those provisions of the Final Rule are arbitrary and capricious under the traditional *State Farm* analysis.

As with the physical separation requirement, this aspect of the Final Rule, which significantly alters the longstanding prior regulatory scheme requires a more detailed justification under *Fox Television*. The counseling and referral restrictions are based in part on factual findings discussed in the Final Rule that contradict those which underlay the 2000 regulations. In 2000, HHS justified its formal rescission of the 1988 "gag rule" on the following grounds: it "endangers women's lives and health by preventing them from receiving complete and accurate medical information"; it "interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients"; "requiring a referral for prenatal care . . . where the client rejected those options would seem coercive and inconsistent with the concerns underlying the 'nondirective' counseling requirement; and it is "consistent with the prevailing medical standards recommended by national medical groups." 65 Fed. Reg. at 41270–75. In contrast, HHS now asserts the restrictions in the Final Rule are warranted because "it is not necessary for women's health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers"; "[r]eferring for adoption or prenatal care, but not for abortion, does not . . . make pregnancy counseling directive"; and the restrictions "will [not] require health care professionals to violate medical ethics, regulations concerning the practice of medicine, or malpractice liability standards." 84 Fed. Reg. at 7746–48. This factual finding conflicts with those underlying the prior HHS guidelines, so HHS must "provide a more detailed justification" for the counseling and referral restrictions. *Fox Television*, 556 U.S. at 515–16. It has not done so. The agency's claim that the restrictions are needed for Title X to comply with conscience laws rings hollow given that its existing regulations already ensure compliance, and in any event the restrictions go far beyond what the conscience laws require.

d. The "Physician or APP" Requirement is Arbitrary and Capricious

Plaintiffs further contend that the requirement in § 59.14(b)(1)(i) that nondirective pregnancy counseling can only be "provided by physicians or advanced practice providers" is arbitrary and capricious, because there is a "complete absence of justification" for the requirement. Essential Mot. at 18; California Mot. at 18–19. Defendants offer two responses, both of which make little sense. First, Defendants point out that the Final Rule is more permissive than the Proposed Rule, because the Proposed Rule restricted pregnancy counseling to physicians only, whereas the Final Rule allows physicians and APPs to take on counseling duties. Opp. at 32–33. This observation is neither here nor there, because neither the Proposed Rule nor the Final Rule explains *why* pregnancy counseling should be limited to physicians or APPs. The physician-and-APP limitation, while more permissive than the physician-only limitation initially proposed, is just as arbitrary.

Second, Defendants claim that "HHS considered which types of health care professionals to include [as qualified to provide pregnancy counseling], and reasonably drew the line at APPs, who have 'advanced medical degrees, licensing, and certification requirements.'" *Id.* (quoting 84 Fed. Reg at 7728 n.41). But this merely recites the Final Rule's definition of APP; again, Defendants cannot point to any part of the Final Rule where HHS explains *why* "advanced medical degrees, licensing, and certification requirements" are necessary to qualify someone to provide pregnancy counseling. The agency certainly did not address voluminous evidence that non-APP personnel with the proper training have long been capably providing pregnancy counseling. *See, e.g.*, Kost Decl. ¶ 86 (citing Guttmacher Institute report that in 2010, 65% of Title X sites "rel[ied] on trained health educators, registered nurses and other qualified providers (excluding physicians and advanced practice clinicians) to counsel patients in selecting contraceptive methods"); Forer Decl. ¶ 29. HHS apparently also disregarded its own recognition of the importance of non-APPs to Title X. *See* 84 Fed. Reg. at 7778 (reporting that non-APPs "were involved with 1.7 million Title X family planning encounters in 2016," approximately one-quarter of the total number of Title X family planning encounters that year).

The APA requires an agency to "articulate a satisfactory explanation for its action." *State*

Farm, 463 U.S. at 43. Moreover, the change in policy based on conflicting factual findings and which engender serious reliance interests require "good reason" and a "more detailed justification." *Fox Television*, 556 U.S. at 515. HHS has articulated no explanation at all for the APP requirement and thus fails both tests. Accordingly, Plaintiffs are likely to succeed on the merits of their claim that § 59.14(b)(1)(i) is arbitrary and capricious.

e. The Removal of the "Medically Approved" Requirement is Arbitrary and Capricious

The 2000 regulations required Title X projects to "[p]rovide a broad range of acceptable and effective *medically approved* family planning methods . . . and services." 42 C.F.R. § 59.5(a)(1) (2000) (emphasis added). The Final Rule removes the "medically approved" language; it simply requires Title X projects to "[p]rovide a broad range of acceptable and effective family planning methods . . . and services." § 59.5(a)(1). Plaintiffs argue HHS failed to provide a reasoned basis for this change. Again, they are correct.

HHS provided one justification for removing the "medically approved" language. According to the agency, "[t]he 'medically approved' language risked creating confusion about what kind of approval is required for a method to be deemed 'medically approved.'" 84 Fed. Reg. at 7741. As Plaintiffs point out, however, HHS cannot identify a single instance in the eighteen years since the 2000 regulations added the "medically approved" requirement where a regulated entity has expressed confusion about the meaning of the term. Indeed, numerous comments submitted during rulemaking demonstrated that Title X providers understood "medically approved" to mean contraceptive methods that have been approved by the Food and Drug Administration, because that is what HHS has made clear it means. Throughout its QFP Guidelines, HHS emphasizes repeatedly that providers of family planning services should provide "a full range of *FDA-approved* contraceptive methods." QFP Guidelines at 7 (emphasis added); *id.* at 2, 10, 11, 23, 24, 39. Numerous medical associations and experts in reproductive health told the agency that they understood "medically approved" to mean "FDA approved." *See, e.g.*, Rich Decl., Exh. E at 2 (Guttmacher Institute); Exh. G at 8 (ACOG); Exh. I at 3 (AMA); Exh. K at 5 (APHA).

The only confusion evinced anywhere in the record is of the agency's own creation. In the Final Rule, instead of citing its QFP Guidelines, HHS hypothesized: "Family planning methods and services are often provided through licensed health care professionals. Thus, it is true of all family planning methods or services provided by Title X providers that at least one medical professional or clinic has 'approved' the method or service, by virtue of providing it to the client." 84 Fed. Reg. at 7732. In disregarding the industry-accepted understanding of "medically approved" and instead suggesting that a single individual—who may be but is not necessarily a "licensed health care professional"—may be able to confer medical approval on a family planning method, HHS is manufacturing confusion where none previously existed. *Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 837 (D.C. Cir. 2006) (finding arbitrary and capricious an agency order that the record revealed to be "a solution in search of a problem").

HHS further feigned ignorance in the Final Rule when it wrote that "[t]he Department also does not understand, and commenters fail to explain, what the addition of 'medically approved' to the definition would mean in practice." 84 Fed. Reg. at 7732. But it later revealed the commenters had explained precisely the import of the "medically approved" language: "Some commenters state the language could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning." *Id.* at 7740. While it recited these concerns, HHS failed to address them. *See Beno v. Shalala*, 30 F.3d 1057, 1074–75 (9th Cir. 1994) ("[A] court should not infer that an agency considered an issue merely because it was raised, where there is no indication that the agency . . . refuted the issue."). Thus, the problem is not that commenters neglected their duty to raise the potential problems with removing the "medically approved" requirement; it is the fact that HHS neglected its duty under the law to consider them.

Accordingly, HHS "offered an explanation for its decision" to remove the "medically approved" language from § 59.5(a)(1) "that runs counter to the evidence before the agency," rendering its action arbitrary and capricious. *State Farm*, 463 U.S. at 43.

f. HHS's Cost-Benefit Analysis is Arbitrary and Capricious

Plaintiffs further contend that the Final Rule as a whole is arbitrary and capricious because HHS conducted and relied upon a deeply flawed cost-benefit analysis. It cited benefits that the Final Rule would confer without any evidentiary basis while disregarding or discounting costs that were supported by the record. *See* California Mot. at 14–18; Essential Mot. at 16–19; *see also* Docket No. 48-1 (amicus brief of the Institute for Policy Integrity at the New York University School of Law).

"As a general rule, the costs of an agency's action are a relevant factor that the agency must consider before deciding whether to act," and "consideration of costs is an essential component of reasoned decisionmaking under the Administrative Procedure Act." *Mingo Logan Coal Co. v. Envtl. Prot. Agency*, 829 F.3d 710, 732–33 (D.C. Cir. 2016); *see Michigan v. E.P.A.*, 135 S. Ct. 2699, 2707–08 (2015) ("Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate."). In promulgating the Final Rule, HHS conducted an economic and regulatory impact analysis as required by "Executive Order 12866 on Regulatory Planning and Review" and "Executive Order 13563 on Improving Regulation and Regulatory Review." 84 Fed. Reg. at 7775. It relied on the cost-benefit analysis in promulgating the Final Rule. *See, e.g.*, *id.* at 7766, 7781–82 (relying on compliance cost estimates to conclude that the new separation requirements will not "have a significant impact on access to services" and to reject commenters' objections that the "requirements will destabilize the network of Title X providers"); *id.* at 7756, 7782–83 (relying on analysis of benefits to assert the Final Rule will "expand[] the type and nature of the Title X providers and ensur[e] the diversity of such providers so as to fill gaps and expand family planning services offered through Title X"). When an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Nat'l Ass'n of Home Builders v. E.P.A.*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012) (reviewing a cost-benefit analysis conducted pursuant to Executive Order 12866 under the arbitrary and capricious standard); *Council of Parent Attorneys*, -- F. Supp. 3d ---, 2019 WL 1082162, at *18 n.11 (same).

HHS's cost-benefit analysis is thus subject to review under the APA. Although such

review is deferential, *Am. Trucking Ass'ns, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 254 (D.C. Cir. 2013), the analysis conducted by HHS here fails even deferential review. On the one hand, the agency proclaimed that a myriad of benefits would flow from the Final Rule without providing any substantiating basis or analysis. On the other, HHS either ignored or dismissed out of hand evidence of the significant costs the Final Rule is likely to inflict that numerous commenters brought to its attention.

i. HHS Did Not Adequately Consider Costs to Patient and Public Health

In response to the Proposed Rule, commenters submitted ample evidence to HHS that the Final Rule's costs on patients and the public will be substantial.

As previously noted, commenters provided substantial evidence that the Final Rule will drive a significant number of current Title X grantees out of the program. Planned Parenthood, whose health centers serve *over 40%* of all Title X patients, "would be forced to discontinue [its] participation in Title X if the Proposed Rule takes effect." Rich Decl., Exh. M at 15–16. Further, "a number of state grantees, including Washington, New York, Hawaii, and Oregon have already put the Department on notice that they would be forced to exit the program if the proposed regulations are finalized, along with other direct grantees." *Id.* at 15. These states combined serve 427,000 Title X patients. *Id.* The loss of Title X funding will force providers to significantly scale down their service capacity or shut down altogether. *See id.*, Exh. C at 5–6. Indeed, the Guttmacher Institute recently estimated that the exit of Planned Parenthood could lead to 1.6 million women losing access to the Title X-funded contraceptive care they currently receive. *Id.*; *see also* Part III.A.1., *supra* (detailing how California providers' capacities will be diminished without Title X funding).

In response, HHS proclaims that it "does not anticipate that there will be a decrease in the overall number of facilities offering [Title X] services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." *Id.* at 7782. As previously discussed, however, this pronouncement is wholly conclusory and unsupported. *See* Part III.A.1., *supra*. HHS provides no evidence to indicate that there are new grantees waiting

in the wings to join Title X, much less enough new grantees to fill the vacuum left by the impending exodus.

Commenters also alerted HHS that the decreased access to reproductive health services precipitated by the Final Rule will lead to an increase in the number of unintended pregnancies and births. In particular, an "increase [in] unplanned and mistimed pregnancies" is a "near certainty under the proposed rule." Brindis Decl., Exh. B at 11. A 2015 Guttmacher Institute report found that "in California, across all publicly funded contraceptive providers . . . it was estimated that, for every seven women who received publicly funded contraceptive services, two pregnancies were averted." *Id.* at 12 n.73. Nationwide, "Title X-funded services helped women avert an estimated 822,300 unintended pregnancies in 2015 alone, thus preventing 387,200 unplanned births and 277,800 abortions." Rich Decl., Exh. L at 31–32. Without the providers of these services, the country's unintended pregnancy rate would have increased by a *whopping 31 percent*. *Id.* The connection between decreased family planning funding and increased rates of unintended pregnancy is reinforced by two further studies. One documented a 27% increase in births among women (who had been using highly effective, publicly funded contraceptive methods) once Texas "severely restricted public funding for family planning." Brindis Decl., Exh. B at 12; *see also* Rich Decl., Exh. K at 4 (American Public Health Association comment noting that "[i]n states that have eliminated Planned Parenthood from their family planning programs, the public health results have been disastrous"). The other surveyed patients in California's publicly funded family planning program and found that individuals would resort to less effective forms of contraceptive if they were forced to pay for family planning services themselves. Brindis Decl., Exh. B at 11. Billions of dollars in public costs would be "associated with . . . unintended pregnancies and outcomes." *Id.* at 12–13.

At three different places in the Final Rule, HHS offers three different, seemingly conflicting responses to this evidence. All three are baseless. First, HHS claims that the Final Rule "is likely to *decrease* unintended pregnancies . . . because clients are more likely to visit clinics that respect their views and beliefs and to use methods that they desire and that fit their individual circumstances." 84 Fed. Reg. at 7743 (emphasis). The agency cites as the basis for this

belief § 59.5(a)(1) of the Final Rule, which clarifies that Title X projects need not provide every family planning method or service. But HHS provides no evidence or analysis suggesting a connection between § 59.1(a)(1) and decreased unintended pregnancies. The agency does not, for example, provide any basis for believing that under the current regulations, patients are choosing not to avail themselves of Title X care because their "views and beliefs" are disrespected by clinics providing nondirective counseling.

Second, HHS insists that "[c]ommenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception." 84 Fed. Reg. at 7785. "On the contrary," according to the agency, "more patients could have access to services because of changes to the program." *Id.* No explanation is offered for this conclusion, nor any analysis to support it. To the extent this conclusory assertion stems from the assumption that the Final Rule will prompt large numbers of new grantees to join Title X, that assumption is debunked by record evidence, as detailed above.

Third, HHS offers an excuse for disregarding the costs associated with higher instances of unintended pregnancies:

> [T]he Department is not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the type of changes to Title X regulations contemplated in this rulemaking and an increase in unintended pregnancies, births, or costs associated with either, much less data that could reliably calculate the magnitude of that hypothetical impact. Therefore, the Department concludes that those are not likely or calculable impacts for the purpose of the Executive Order.

84 Fed. Reg. at 7775. This rationale does not withstand even deferential scrutiny.

For one thing, "[t]he mere fact that the . . . effect[] [of a rule] is *uncertain* is no justification for *disregarding* the effect entirely." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004) (emphases in original). Yet that is the exact mistake HHS makes here in concluding that unintended pregnancies "are not likely" because it believes the effects of the Final Rule are difficult to quantify. HHS cannot simply disregard costs that are uncertain or difficult to quantify. Its "Guidelines for Regulatory Impact Analysis" set forth in detail how the agency is supposed to "address[] outcomes that cannot be quantified but may have important

implications for decision-making."[17] HHS Guidelines at 47. Per the Guidelines, "[i]f quantification is not possible, analysts *must* determine how to best provide related information." *Id.* (emphasis added); *see id.* at 47–51 (laying out various approaches for incorporating non-quantified effects into regulatory impact analysis). "At minimum, analysts should list significant nonquantified effects in a table and discuss them qualitatively." *Id.* at 51. HHS failed to do even that here. In its cost-benefit accounting table, the agency listed the total "Non-quantified Costs" of the Final Rule as, simply, "None." *Id.* at 7777. "None" more aptly describes the extent of HHS's analysis.

Commenters also informed HHS that the exodus of Title X providers will reduce patients' access to health services beyond family planning, and give rise to attendant health costs. "Apart from the delivery of family planning care, Title X providers have come to play an essential and important role in providing any number of other vital health services for low-income Americans," including "screenings for cervical cancer, diabetes, high blood pressures, and sexually transmitted infections (STIs), among a range of other services aimed at primary prevention and referral." Brindis Decl., Exh. B at 3.[18] "[F]or many low-income women, visits to a family planning provider are their only interaction with the health care system at all," so a reduction in the number of Title X sites would "cut off many people" from a critical health resource. *Id.*; *see* Rich Decl., Exh. M at 16 (Planned Parenthood comment explaining that "[f]ifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and may have nowhere else to go to access essential health services without Planned Parenthood"). Commenters cited the case study of a rural Indiana county in which the Planned

[17] Notably, the HHS Guidelines specifically list changes in "the type or quality of information available and its dissemination" effectuated by an agency action as a type of cost that is difficult to quantify but that HHS must nevertheless analyze. HHS Guidelines at 48. Absent from the Final Rule, however, is any substantive discussion of how the Final Rule's counseling and referral restrictions might create informational costs.

[18] HHS itself trumpets these benefits of the current Title X program. *See* Office of Population Affairs, *Title X Family Planning Annual Report 2017 Summary* ES-2, (August 2018) ("Title X-funded cervical and breast cancer screening services are necessary for early detection and treatment," and "Title X-funded STD and HIV services provide testing necessary for preventing disease transmission and adverse health consequences.").

Parenthood facility closed in 2013 due to cuts to public health funding. Brindis Decl., Exh. B at 6. Without the facility, the county lost free HIV testing services and almost immediately experienced "one of the largest and most rapid HIV outbreaks the country has ever seen." *Id.* at 6–7 (citation omitted).

In response to this evidence, HHS wrote:

> Based on the Department's best estimates, it anticipates that the net impact on those seeking services from current grantees *will be zero*, as any redistribution of the location of facilities will mean that some seeking services will have shorter travel times and others seeking services will have longer travel times to reach a facility. Additionally, as a result of this final rule, the Department anticipates expanded competition that will engender new and/or additional grantees who will serve previously unserved or underserved areas, likely expanding coverage and patient access to services.

84 Fed. Reg. at 7782 (emphasis added).

The agency did not explain how it arrived at its "best estimates,"[19] or how it reached the seemingly speculative conclusion that the Final Rule would result merely in the "redistribution" of services and that because of the entrance of new grantees "the net impact on those seeking services from current grantees will be zero." The lack of any evidence or analysis supporting HHS's supposition that everything will even out is particularly conspicuous in the face of evidence that "other types of Title X sites would need to increase their client caseloads by 70 percent" just to compensate for the exit of Planned Parenthood from Title X. Rich Decl., Exh. M at 16. HHS's "naked conclusion . . . is not enough." *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 565 (D.C. Cir. 2010).

HHS similarly failed to take account of the costs that will result from its decision to remove the requirement in § 59.5(a)(1) that the family planning methods and services provided under Title X be "medically approved." Commenters notified the agency that this change "could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over

[19] The HHS Guidelines expressly describe "reductions in government payments to hospitals" as a type of "transfer cost" that "should be addressed in the benefit-cost analysis, if significant," because "the affected hospitals may accept fewer patients or use less expensive treatments, in turn affecting health outcomes." HHS Guidelines at 23.

science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning." 84 Fed. Reg. at 7740; *see* Rich Decl., Exh. I at 3; *id*., Exh. Q at 2. Commenters specifically warned HHS that the change "seem[s] to open the door to entities like antiabortion counseling centers (or 'crisis pregnancy centers')" that "commonly do not have any medical staff and are not able or willing to provide many or all modern and FDA-approved methods of contraception." Rich Decl., Exh. E at 15. The agency did not address any of these potential costs to patient health.

ii. HHS Did Not Adequately Consider Compliance Costs

HHS's assessment of the costs to regulated entities of complying with the Final Rule is also inadequate, for the reasons discussed in Part III.C.2.b., *supra*.

iii. The Claimed Benefits are Unsubstantiated and Speculative

On the other side of the cost-benefit equation, HHS contends that the Final Rule is expected to "[e]nhance[] compliance with statutory requirements"; result in an "[e]xpanded number of entities interested in participating in Title X"; and "[e]nhance[] patient service and care." 84 Fed. Reg. at 7777, 7782. But HHS provided no evidence in support of any of these claims; nor did it provide any estimates of the expected magnitude of these supposed benefits. Instead, each of these claimed benefits has been shown to "run[] counter to the evidence before the agency." *State Farm*, 463 U.S. at 43. In the absence of any attempt by HHS to quantify or even explain with any substantive analysis the Final Rule's claimed benefits, it cannot be said that there has been a "reasoned determination" that the benefits justify the costs. "[R]easoned decisionmaking requires assessing whether a proposed action would do more good than harm." *Mingo Logan Coal Co. v. Envtl. Prot. Agency*, 829 F.3d 710, 732 (D.C. Cir. 2016).

On the whole, the determination by HHS that the asserted but unsubstantiated, undocumented, and speculative benefits of the Final Rule outweigh its likely substantial costs indicates the agency "put a thumb on the scale by [over]valuing the benefits and [under]valuing the costs." *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). The cost-benefit analysis is undermined by "serious flaw[s]" that "render the rule unreasonable" in its entirety under the APA. *Nat'l Ass'n of Home Builders*, 682 F.3d at

1039–40; *see State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (holding that agency action was arbitrary and capricious where the agency "only consider[ed] one side of the equation" in its cost-benefit analysis).

3. HHS Did Not Violate Notice and Comment Procedures

Essential Access makes one final claim under the APA. It contends that Defendants did not comply with the APA's notice and comment requirements because the "comprehensive primary care provider" and "physician and APP" requirements in the Final Rule are not logical outgrowths of the proposed rule. *See* Essential Mot. at 19–20.

The APA generally requires an agency to engage in notice and comment as part of its rulemaking process. *See* 5 U.S.C. § 553(b). The agency must publish a notice of proposed rulemaking in the Federal Register and notify the public of, *inter alia*, "the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* § 553(b)(3). "Agencies are free—indeed, they are encouraged—to modify proposed rules as a result of the comments they receive." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004). However, "an agency's proposed rule and its final rule may differ only insofar as the latter is a 'logical outgrowth' of the former." *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (citation omitted). A final rule is considered a logical outgrowth of a proposed rule "only if interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) (quoting *Ne. Md. Waste Disposal Auth.*, 358 F.3d at 952); *Envtl. Def. Ctr., Inc. v. U.S. E.P.A.*, 344 F.3d 832, 851 (9th Cir. 2003).

a. The "Comprehensive Primary Care Provider" Requirement is a Logical Outgrowth of the Proposed Rule

According to Essential Access, the requirement in § 59.14(b)(1)(ii) of the Final Rule that Title X projects can only refer patients to "licensed, qualified, comprehensive primary health care providers" is not a logical outgrowth of the Proposed Rule, which permitted referrals to "licensed, qualified, comprehensive health service providers." 83 Fed. Reg. at 25531. That is, Essential

Access objects that the Proposed Rule did not specify that "comprehensive health service providers" must provide "primary care services." Essential Mot. at 20.

Essential Access has not cited any authority for the proposition that "comprehensive primary care" is meaningfully different from "comprehensive care," such that interested parties could not have anticipated that the Final Rule would incorporate the former term. Essential Access insists that language in the Final Rule "contemplates that 'comprehensive' health care services can be 'primary' or 'prenatal.'" Essential Reply at 8 (citing 84 Fed. Reg. at 7761). But the actual language in the Final Rule does not draw a distinction between "primary" comprehensive care and "prenatal" comprehensive care; it merely indicates that "comprehensive primary care" can include prenatal care. *See* 84 Fed. Reg. at 7761 ("The Department is finalizing § 59.14(b)(1)(ii) to allow Title X providers to give a single list of providers to any pregnant woman. This list will contain licensed, qualified, comprehensive primary health care providers (including providers of prenatal care)."). Essential Access has not shown a likelihood of success on its claim that § 59.14(b)(1)(ii) of the Final Rule is not a logical outgrowth of the Proposed Rule.

b. The "Physician or APP" Requirement is a Logical Outgrowth of the Proposed Rule

Essential Access also argues the requirement in § 59.14(b)(1) of the Final Rule that any nondirective pregnancy counseling under Title X can only be "provided by physicians or advanced practice providers" is not a logical outgrowth of the Proposed Rule. Essential Mot. at 20. It is true, as Essential Access points out, that the term "advanced practice provider" does not appear anywhere in the Proposed Rule. But that is because the Proposed Rule was more restrictive than the Final Rule; under the former, only physicians were permitted to provide pregnancy counseling:

> [A] doctor, though not required to do so, would be permitted to provide nondirective counseling on abortion. Such nondirective counseling would not be considered encouragement, promotion, or advocacy of abortion as a method of family planning, as prohibited under section 59.16 of this proposed rule. Moreover, a doctor would also be permitted to provide a list of licensed, qualified, comprehensive health service providers, some (but not all) of which provide abortion in addition to comprehensive prenatal care.

83 Fed. Reg. at 25518. In summarizing the changes between the Proposed Rule and the Final Rule, HHS wrote, "as a result of comments on the type of medical professional who could provide nondirective counseling and referrals under the proposed rule, . . . the Department has determined that, in addition to medical doctors, advanced practice providers (APPs) may provide nondirective counseling and referrals." 84 Fed. Reg. at 7727–28.

The Proposed Rule signaled that the agency was considering limiting counseling responsibilities to individuals with advanced medical degrees, so it cannot be said that the Final Rule "finds no roots in the agency's proposal." *Envtl. Integrity Project v. E.P.A.*, 425 F.3d 992, 996 (D.C. Cir. 2005); *see Hodge v. Dalton*, 107 F.3d 705, 712 (9th Cir. 1997) (holding that a final rule "in character with the original proposal" is a logical outgrowth). Moreover, the Final Rule indicates that the Proposed Rule engendered "comments on the type of medical professional who could provide nondirective counseling and referrals." 84 Fed. Reg. at 7727–28. Essential Access argues that "[h]ad HHS provided proper notice, the public may have expressed concerns . . . [that] the definition of APP is much too narrow, and excludes professionals who currently provide the bulk of pregnancy options counseling at Title X centers." Essential Mot. at 20. However, any such comments about the ability of certain categories of professionals to provide counseling could equally have been submitted to the Proposed Rule because those professionals were already excluded under the Proposed Rule.

Accordingly, Essential Access has not shown that a likelihood that § 59.14(b)(1) of the Final Rule is not a logical outgrowth of the Proposed Rule.

4. Plaintiffs' Remaining Claims

Because the Court finds that Plaintiffs have established that they are likely to succeed on the merits of their "not in accordance with law" and "arbitrary and capricious" claims under the APA, the Court will not reach their constitutional claims at this time.

D. Scope of Injunction

Plaintiffs have made a strong showing on each of the *Winter* factors, and accordingly are entitled to preliminary relief. They ask the Court to grant a nationwide injunction. California Mot. at 25; Essential Mot. at 33–35. Defendants respond that any injunctive relief should be

limited to Plaintiffs, *i.e.*, to the state of California. Opp. at 46–50.

The recent Ninth Circuit ruling in *California v. Azar*, 911 F.3d 558 (9th Cir. 2018) provides guidance on how a district court should exercise its discretion in crafting an injunction. *Azar* emphasized that while "'there is no bar against . . . nationwide relief in federal district court or circuit court,' such broad relief must be 'necessary to give prevailing parties the relief to which they are entitled.'" *Id.* at 582 (quoting *Bresgal v. Brock*, 843 F.2d 1163, 1170–71 (9th Cir. 1987)). The Ninth Circuit determined that the nationwide injunction it was reviewing was overbroad because "while the record before the district court was voluminous on the harm to the plaintiffs, it was not developed as to the economic impact on other states." *Id.* at 584. The court instructed that "[d]istrict judges must require a showing of nationwide impact or sufficient similarity to the plaintiff states to foreclose litigation in other districts." 911 F.3d at 584.

Plaintiffs have supplied ample evidence of the Final Rule's anticipated impact within California. *See* Part III.A., *supra*. They offer three reasons why a nationwide injunction is necessary to afford them adequate relief. First, they assert that any violation of the APA "compel[s]" a nationwide injunction. Essential Reply at 14. Notably, however, *Azar* found that the plaintiffs there had shown a likelihood of success on their APA claims, and nonetheless ruled that a nationwide injunction was overbroad. *See* 911 F.3d at 575–81. This suggests that, notwithstanding an APA violation, this Court still must assess whether "[t]he circumstances of this case dictate a narrower scope" of relief. *Id.* at 584.

Plaintiffs' second argument is that they *have* provided sufficient evidence of the Final Rule's nationwide impact to support a broad injunction, and in particular cite to the Kost and Brindis declarations. *See* Essential Reply at 15 (citing Kost Decl. ¶¶ 76–78; Brindis Decl. ¶¶ 80–93). While the portions of the declaration on which Plaintiffs rely address the many Title X providers around the country will leave the program because of the Final Rule, the record does not indicate that preserving the current Title X network in other states is "necessary to redress the injury shown by the *[P]laintiff[s]*." *Azar*, 911 F.3d at 584 (emphasis added). Both Plaintiffs are from California. Neither Plaintiff has offices or operations outside of California. And nearly all the harms they document are focused on California. *See, e.g.*, Cantwell Decl. ¶ 32; Tosh Decl. ¶

52. It is difficult to conduct a balance of hardship as to effects outside of California on this record.

Third, Plaintiffs argue that "Title X funding recipients draw from a single pool of funding, such that '[t]he conditions imposed on one can impact the amounts received by others.'" California Reply at 15 (quoting *City of Chicago v. Sessions*, 888 F.3d 272, 292 (7th Cir. 2018)). According to Plaintiffs, recipients of Title X funding are "interconnected" because if Title X grantees in some areas claim less funding, grantees in other areas would receive commensurately more. Even so, however, an injunction limited to California would allow grantees within the state to maintain and deploy their regular allotment of Title X funds; grantees in other states would not be able to take away California's funds. It is difficult to discern on this record how a preliminary injunction limited to California will affect other states in a way that will harm Plaintiffs and their clients in California. In short, Plaintiffs have not shown at this juncture that a nationwide injunction is necessary to protect their interests. The Court cannot find, on this record, that Plaintiffs have made "a showing of nationwide impact" to warrant nationwide relief. *Azar*, 911 F.3d at 583.

Accordingly, Plaintiffs' motions for preliminary injunction are **GRANTED** and the Final Rule is **ENJOINED** as to enforcement in the state of California.

This order disposes of *California* Docket No. 26 and *Essential Access* Docket No. 25.

IT IS SO ORDERED.

Dated: April 26, 2019

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California